ANTICIPATED ACQUISITION BY THERAMEX HQ UK LIMITED OF THE EUROPEAN RIGHTS TO VIATRIS' FEMOSTON AND DUPHASTON PRODUCTS

Decision on relevant merger situation and substantial lessening of competition

ME/7073/23

The Competition and Markets Authority's decision on relevant merger situation and substantial lessening of competition under section 33(1) of the Enterprise Act 2002 given on 4 April 2024. Full text of the decision published on 16 May 2024.

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SUMMARY

OVERVIEW OF THE CMA'S DECISION

1. The Competition and Markets Authority (**CMA**) has found that the acquisition by Theramex HQ UK Limited (**Theramex**) of the European Rights to Viatris Inc's (**Viatris**) Femoston and Duphaston Products (the **Rights**), gives rise to a realistic prospect of a substantial lessening of competition (**SLC**) as a result of horizontal unilateral effects arising from the loss of existing competition in the supply of systemic hormone replacement therapy (**HRT**) in relation to menopausal symptoms and loss of future competition in the supply of dydrogesterone in the UK.

2. On 20 August 2023, Theramex entered into an Asset Purchase Agreement (**APA**) with Viatris to acquire the Rights in the UK, the EEA, Switzerland and certain other European countries. The CMA refers to this acquisition as the **Merger**. Theramex and the Rights are together referred to as the **Parties** and, for statements relating to the future, the **Merged Entity**.

3. As the CMA has found that the Merger gives rise to a realistic prospect of an SLC, the Parties have until 11 April 2024 to offer undertakings in lieu of a reference (**UILs**) to the CMA that will remedy the competition concerns identified. If no such undertakings are offered, then the CMA will refer the Merger for a phase 2 investigation pursuant to sections 33(1) and 34ZA(2) of the Enterprise Act 2002 (the **Act**).

Who are the businesses and what products/services do they provide?

4. Theramex is a global women's health pharmaceutical company headquartered in London. Its portfolio includes various HRT products, which treat a range of the symptoms of menopause.

5. Viatris is a global pharmaceutical and healthcare corporation headquartered in Pennsylvania.

6. The CMA focused its assessment on systemic HRT products as this is where the Parties overlap. Systemic HRT is the most commonly used treatment for managing menopausal symptoms, such as hot flushes, joint pain, anxiety and mood swings. The main component of HRT is the hormone oestrogen. Patients who have had a hysterectomy take oestrogen-only HRT, while those who have not had a hysterectomy also take progestogen to protect the lining of the womb from the effect of oestrogen. HRT treatments can be combined (ie contain both oestrogen and progestogen) or separate and, in the case of combined treatments, may deliver progestogen either continuously or sequentially, depending on the patient's

needs. HRT treatments can be taken orally as pills or applied transdermally by means of a patch, gel or spray: the choice will depend on the patient's medical needs and personal preferences.

7. The products which are the subject of the Merger are Viatris' Femoston and Duphaston. Femoston is a combined oral treatment containing oestrogen and progestogen (based on the dydrogesterone molecule) which is available in two forms, continuous (**Femoston Conti**) and sequential (referred to here as **Femoston Sequi**), both of which are available in the UK. Femoston Sequi and Femoston Conti are referred to together as **Femoston**. **Duphaston** is an oral progestogen (based on the dydrogesterone molecule) which is widely used in mainland Europe but does not currently have marketing authorisation (**MA**) in the UK.

Why did the CMA review this merger?

8. The CMA's primary duty is to seek to promote competition for the benefit of consumers. It has a duty to investigate mergers that could raise competition concerns in the UK, provided it has jurisdiction to do so.

9. Theramex and the Rights are both active in the supply of systemic HRT products in the UK, with a combined share of supply of [40-50]% and an increment of [5-10]% by value. The CMA has jurisdiction to review a merger where the share of supply test is met (requiring that the Parties together supply at least 25% of a particular good or service supplied in the UK, and there is an increment to the share of supply). On the basis of the Parties' shares of supply of systemic HRT products, the CMA considers that the share of supply test is met.

What evidence did the CMA look at?

10. In assessing the Merger, the CMA considered a wide range of evidence in the round.

11. The CMA received several submissions and responses to information requests from the Parties. The CMA gathered information about the rationale for the Merger, the Parties' existing products and Theramex's plans to introduce new products in the UK. The CMA also examined the Parties' own internal documents, which show how they run their business and how they view their rivals in the ordinary course of business.

12. The CMA spoke to and gathered evidence from other companies and organisations to understand better how HRT is prescribed in the UK, the competitive landscape and their views on the impact of the Merger. In particular, the CMA received evidence from menopause specialist clinicians, relevant regulatory health agencies, public bodies as well as Integrated Care Boards

(**ICBs**) and equivalent bodies and other pharmaceutical companies active in the UK market for systemic HRT.

What did the evidence tell the CMA…

…about what would have happened had the Merger not taken place?

13. In order to determine the impact that the Merger could have on competition, the CMA considered what would have happened had the Merger not taken place. This is known as the counterfactual.

14. In this case, the CMA found that, absent the Merger:

    (a) In the case of Femoston Sequi and Femoston Conti, there is evidence that another purchaser would carry on supplying these products in the UK; and

    (b) In the case of Duphaston, there is evidence that another purchaser would have acquired the rights to supply this product in the UK, while Theramex would have gone on to launch a generic version of dydrogesterone in partnership with a third party.

…about the effects on competition of the Merger?

15. The CMA looked at how the Merger could affect competition in (i) the supply of systemic HRT in the UK; and (ii) the supply of dydrogesterone in the UK.

Theory of harm 1: horizontal unilateral effects arising from the loss of competition in the supply of systemic HRT in the UK

16. The CMA considered whether the combination of Theramex and the Rights might be expected to lessen competition substantially in the supply of systemic HRT in the UK. Theramex has the largest market share in systemic HRT in the UK. The UK market for systemic HRT is highly concentrated: the two largest players have around [70-80%] of sales. The effect of the Merger would be to increase Theramex's share by [5-10]%, a significant increase in a concentrated market, and to remove one of the few other material competitive constraints. The CMA found that the constraint imposed by other HRT suppliers is limited. In addition, while patient needs may differ and HRT products are differentiated, the CMA found that products owned by Theramex closely compete with the products being acquired. This includes Theramex's Bijuve, a combined continuous oral product that competes closely with Femoston Conti. The CMA therefore found that the Merger gives rise to a realistic prospect of an SLC as a result of horizontal unilateral effects arising from the loss of competition in the supply of systemic HRT in the UK.

Theory of harm 2: loss of future competition in the supply of dydrogesterone

17. Unilateral effects may also result in a loss of future competition in relation to the supply of dydrogesterone, a progestogen-only product, in the UK. As explained above, the Rights include the rights to Duphaston, a dydrogesterone product currently marketed in Europe but not in the UK. The CMA found that there is demand for a dydrogesterone product in the UK and that an alternative purchaser of the Rights would have been likely to launch Duphaston in the UK. In addition, as explained above, the CMA found evidence that Theramex was likely to launch a generic dydrogesterone product in the UK, absent the Merger. In that scenario, the owner of Duphaston and Theramex would have been expected to compete with respect to the supply of dydrogesterone.

18. On this basis, the CMA found that absent the Merger, there may have been greater competition to enter or expand dydrogesterone products in the UK market, and more new products may have been introduced. The CMA therefore found that the Merger gives rise to a realistic prospect of an SLC in relation to loss of future competition in the supply of dydrogesterone in the UK.

What happens next?

19. As a result of these concerns, the CMA believes the Merger gives rise to a realistic prospect of SLCs as a result of horizontal unilateral effects arising from the loss of existing competition in the supply of systemic HRT and loss of future competition in the supply of dydrogesterone. The Parties have until 11 April 2024 to offer an undertaking which might be accepted by the CMA to address the SLCs. If no such undertaking is offered, or the CMA decides that any undertaking offered is insufficient to remedy its concerns to the phase 1 standard, then the CMA will refer the Merger for an in-depth phase 2 investigation pursuant to sections 33(1) and 34ZA(2) of the Act.

ASSESSMENT

1. PARTIES, MERGER AND MERGER RATIONALE

20. Theramex, the acquirer, is a women's health pharmaceutical company headquartered in London.[1][2] Its portfolio includes various HRT products, which treat a range of the symptoms of menopause and perimenopause.[3] Theramex's turnover in 2022 was £[✂] worldwide and £[✂] in the UK.[4] Theramex's systemic HRT products in the UK include:

(a) Bijuve, a combined continuous oral product containing a body identical estradiol and progesterone;

(b) Everol Conti and FemSeven Conti, combined continuous transdermal patches;

(c) Everol Sequi and FemSeven Sequi, combined sequential transdermal patches; and

(d) Evorel and FemSeven, oestrogen-only transdermal patches.

Theramex also plans to launch [✂] in the UK in 2024, which is an [✂] that it sells in other countries.

21. Viatris, the seller, is a global pharmaceutical and healthcare corporation headquartered in Pennsylvania.[5] The acquisition concerns certain rights, assets and title to commercialise the following off-patent HRT products within Viatris' wider women's healthcare portfolio:

(a) Femoston Sequi, a fixed dose combination systemic sequential oral product containing oestradiol and dydrogesterone;

(b) Femoston Conti, a fixed dose combination systemic continuous oral product containing estradiol and dydrogesterone; and

(c) Duphaston, a systemic oral progestogen HRT product containing dydrogesterone.

[1] Theramex is indirectly controlled by Carlyle and PAI Partners through CEP V Investment 25 S.à.r.l. (with CIM Europe S.à.r.l. acting as fund manager) and Galaxy Acquisitions S.à.r.l. (with PAI Partners S.à.r.l. acting as fund manager).
[2] Final Merger Notice submitted to the CMA on 5 February 2024 (**FMN**), paragraph 3.
[3] FMN, paragraph 3.
[4] FMN, paragraph 69.
[5] FMN, paragraph 4.

22. The turnover of the Rights in 2023 was £[✂] worldwide and £[✂] in the UK.[6]

23. On 20 August 2023, Theramex entered into an APA with Viatris to acquire the Rights in the UK, the EEA, Switzerland, [✂].[7]

24. The Parties informed the CMA that the Merger was notified to competition authorities in Austria and Bulgaria and clearance has been granted by both authorities.[8]

25. In terms of rationale, Viatris submitted that it has made a strategic decision to divest its women's healthcare business to focus on other areas. In parallel with the Merger, Viatris entered into an agreement with Insud Pharma to acquire substantially the rest of its women's healthcare business, excluding the Rights. The sale to Insud Pharma completed on 12 March 2024. Theramex submitted that its rationale for the Merger is to ensure that a broad and varied range of HRT products is available and to complement its existing portfolio of transdermal HRT products with oral products.[9]

26. While some of Theramex's internal documents support its stated rationale,[10] the CMA has also seen evidence that the Rights are not entirely complementary to Theramex's existing portfolio, and they may be the closest substitutes to certain of Theramex's products whose growth and/or development may be impaired because of the Merger.[11]

2. PROCEDURE

27. The CMA's mergers intelligence function identified the Merger as warranting an investigation.[12]

28. The CMA commenced its phase 1 investigation on 6 February 2024. As part of its phase 1 investigation, the CMA gathered a significant volume of evidence from the Parties. In response to targeted information requests, the CMA received and reviewed internal documents from Theramex and Viatris to understand the competitive dynamics in HRT in the UK. The Parties also had opportunities to make submissions and comment on the CMA's emerging thinking throughout the phase 1 investigation. For example, the CMA invited the Parties to attend an Issues Meeting on 12 March 2024, and the Parties subsequently submitted their

[6] Parties' response to CMA Request for Information (RFI 6), 26 March 2024. Converted using Bank of England average 2023 exchange rate of USD1.2434 to GBP1.
[7] FMN, paragraph 19.
[8] FMN, paragraph 48.
[9] FMN, paragraph 31.
[10] Annex Q9.001 to the FMN, slide 2; Annex LL00018252 to the Parties' response to the section 109 notice dated 13 October 2023 (**s109 1**), slide 19; and Annex LL00017006 to the Parties' response to s109 1, page 2.
[11] See for example, Annex LL00016721 to the Parties' response to s109, slide 2.
[12] Mergers: Guidance on the CMA's jurisdiction and procedure (**CMA2**), January 2021 (as amended on 4 January 2022), paragraphs 6.4–6.6.

views in writing. The CMA also gathered evidence from other market participants, such as expert clinicians, competitors and representative of the British Menopause Society (**BMS**)[13], National Health Service (**NHS**), Department of Health and Social Care (**DHSC**) and Medicines and Healthcare products Regulatory Agency (**MHRA**). The evidence the CMA has gathered has been tested rigorously, and the context in which the evidence was produced has been considered when deciding how much weight to give it.

29. This evidence has been referred to within this Decision as relevant.

30. The Merger was considered at a Case Review Meeting.[14]

3. JURISDICTION

31. As a result of the Merger, Theramex will acquire the rights to carry on the business of commercialising Femoston and Duphaston in Europe (including the UK), which amounts to an enterprise within the meaning of the Enterprise Act 2002 (the **Act**). Theramex also constitutes an enterprise within the meaning of the Act. As a result, the CMA considers that enterprises carried on by Theramex will cease to be distinct from enterprises carried on by Viatris within the meaning of section 26 of the Act.

32. Theramex and the Rights overlap in the supply of systemic HRT products in the UK, with a combined share of supply of [40-50]% and an increment of [5-10]% by value (see section 6.3.2.1.3.1). The CMA therefore considers that the share of supply test in section 23 of the Act is met.

33. The APA provides for separate completion in the UK on the one hand (**UK Closing**), and in the EEA, Switzerland, [✂] on the other hand (**ROW Closing**). It is apparent from the APA that UK Closing and ROW Closing are interrelated, including because [✂].[15] ROW Closing took place on 8 December 2023 whilst UK Closing remains outstanding. Accordingly, the CMA considers that the arrangements contemplated by the APA are 'in progress or in contemplation' and, if carried into effect, will result in the creation of a relevant merger situation for the purposes of section 36 of the Act.

34. The initial period for consideration of the Merger under section 34ZA(3) of the Act started on 6 February 2024 and the statutory 40 working day deadline for a decision is therefore 4 April 2024.

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[13] BMS is the specialist authority for menopause and post reproductive health in the UK. Established in 1989, the BMS educates, informs and guides healthcare professionals, working in both primary and secondary care, on menopause and all aspects of post reproductive health. https://thebms.org.uk/about-the-charity/our-work/
[14] CMA2, from page 65.
[15] Annex Q8.001 to the FMN, section 6.02(b)(iii).

4. COUNTERFACTUAL

35. The CMA assesses a merger's impact relative to the situation that would prevail absent the merger (ie the counterfactual).[16]

36. In an anticipated merger, the counterfactual may consist of the prevailing conditions of competition, or conditions of competition that involve stronger or weaker competition between the parties to a merger than under the prevailing conditions of competition.[17] In determining the appropriate counterfactual, the CMA will generally focus on potential changes to the prevailing conditions of competition only where there are reasons to believe that those changes would make a material difference to its competitive assessment.[18]

37. The Merger Assessment Guidelines state that, in phase 1 investigations, if the CMA must consider multiple potential counterfactual scenarios where each of those scenarios is a realistic prospect, it will choose the one where the merger firms exert the strongest competitive constraint on each other, and where third parties exert the weakest competitive constraints on the merger firms.[19]

38. The Parties submitted that, absent the Merger, Viatris would either have retained the Rights or sold the Rights to another purchaser (whether as a standalone sale or as part of the divestment of its wider women's healthcare business).[20] The CMA understands that during Viatris' sales process for its women's healthcare business, [✂] bidders made an offer that included the Rights – [✂].

39. The CMA considers the potential counterfactual scenarios for each of Femoston and Duphaston in turn below.

4.1.1 Femoston

40. The Parties submitted that, absent the Merger, Viatris would have considered divesting Femoston to another willing purchaser. In the alternative, Viatris would have retained Femoston and continued to supply it in the UK.[21]

41. The CMA notes that Viatris has divested substantially the rest of its women's healthcare business in order to focus on other areas (see paragraph 25 above). Femoston was a profitable business in the UK and did, in fact, attract a bid from another potential purchaser. The CMA considers that the more likely counterfactual is one in which Femoston would have been sold to a third-party purchaser who would have continued to operate the business. The CMA did not

[16] Merger Assessment Guidelines (**CMA129**), March 2021, paragraph 3.1.
[17] CMA129, paragraph 3.2.
[18] CMA129, paragraph 3.9.
[19] CMA129, paragraph 3.12.
[20] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 38.
[21] FMN, paragraphs 84–85.

receive any evidence from the Parties or third parties to indicate that the sale of Femoston to [✂] or another purchaser would have changed the prevailing conditions of competition. Accordingly, in line with the Merger Assessment Guidelines[22], the CMA considers that the prevailing conditions of competition is the relevant counterfactual in relation to Femoston.

42. The CMA considered the Parties' submission that, in the alternative, Femoston could have been retained by Viatris. Given that Viatris had divested substantially the rest of its women's health business, it is not clear whether Viatris would have continued to support Femoston at the same level.[23] The CMA did not, however, need to consider the possible retention of the business by Viatris in detail given the CMA's finding that the more likely counterfactual was the sale to an alternative purchaser, and the approach set out in the Merger Assessment Guidelines of relying on the most competitive realistic counterfactual in a phase 1 assessment.[24]

4.1.2 Duphaston

43. Duphaston was first launched in the UK in 1961 and has been off-patent since at least the 1980s. However, Duphaston has not had an MA in the UK since 2008 and as a result it has not been supplied in the UK for over 15 years (see paragraph 234 below). The Parties submitted that Viatris had no plans to reapply for an MA and that this would be inconsistent with its strategic decision to divest substantially all of its women's healthcare business.[25] The CMA did not see any evidence that, absent the Merger, Viatris would have relaunched Duphaston in the UK.

44. Based on the evidence received and its analysis to date, the CMA considered whether, absent the Merger:

(a) a third party would have acquired and re-launched Duphaston in the UK; and

(b) Theramex would have launched a second generic dydrogesterone product in the UK in partnership with [✂].

4.1.2.1 Likelihood of a third party entering with Duphaston

45. The Parties submitted that, absent the Merger, Viatris would not relaunch Duphaston and there is no evidence to support the proposition that Viatris would have sold the Rights to a third party which would relaunch Duphaston in the UK.

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[22] CMA129, paragraph 3.12.
[23] A third party told the CMA that bigger players in this market may find it easier to ensure a secure supply of active ingredients or ensure that their orders are prioritised by the manufacturing partner. Third party response to RFI, January 2024.
[24] CMA129, paragraph 3.12.
[25] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraphs 36 and 37.

Viatris did not receive an offer for the Rights from any potential purchasers other than [✂].[26]

46. Viatris submitted that [✂] had no real interest in acquiring the Rights.[27] Viatris told the CMA that [✂] was invited to bid for the Rights in order to ensure a competitive bidding process and only [✂].[28] Viatris also submitted that [✂]'s offer of USD [✂] for the Rights [✂].[29] Viatris told the CMA that it understood [✂]'s offer to be based on [✂].[30] As negotiations progressed, Viatris decided [✂] to separate the sale of the rights to Duphaston and Femoston from the rest of its women's healthcare business.[31]

47. The CMA considers that, absent the Merger, Viatris would have had strong incentives to agree a sale of Duphaston to any purchaser with a credible offer because it had made a strategic decision to divest its women's healthcare business and focus on other areas. While the offer made by [✂] for the Rights was [✂] than that made by Theramex, the CMA did not find evidence that Viatris considered [✂]. There is no requirement for the CMA to restrict its counterfactual to an alternative purchaser willing to pay the same or a similar price to that agreed in the Merger. Therefore, absent the Merger, the CMA considers it realistic that Viatris would have agreed a sale to [✂] or any other purchaser with a credible offer.

48. As regards the incentives to relaunch Duphaston, the CMA has not seen evidence that Viatris would relaunch Duphaston in the UK [✂]. The CMA assessed the incentives of [✂] and alternative purchasers to relaunch Duphaston. Based on third-party evidence, the CMA understands that there is high unmet clinical demand for Duphaston the UK (see paragraph 240 below). Following a period of low demand owing to the public perception of HRT as risky, there has been a resurgence in recent years. Demand has increased significantly since the National Institute for Health and Care Excellence (**NICE**) updated its guidance on menopause and systemic HRT in 2015,[32] and now often it outstrips supply. Therefore, whilst there may not have been a commercial case for relaunching Duphaston in the UK during the period of low demand, the CMA considers that this has now changed, particularly given Duphaston's success in Europe.

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[26] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 41.
[27] Parties' response to Issues Letter, paragraph 22(b).
[28] Parties' response to Issues Letter, page 7.
[29] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 40(vi)(a); Parties' response to Issues Letter, page 7-8.
[30] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 40(vi)(a).
[31] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 39.
[32] NICE provides national guidance and advice to improve health and social care. NICE is an executive non-departmental public body, sponsored by the Department of Health and Social Care. The NICE HRT guidance can be found here: https://www.nice.org.uk/guidance/ng23

49. The CMA considered whether there are regulatory barriers that would mean a third party would be unlikely to re-launch Duphaston in the UK. The evidence reviewed by the CMA indicates that the regulatory requirements for relaunching Duphaston would not pose a significant barrier. The existing European MAs for Duphaston would facilitate the UK MA process. For example:

(a) A third party told the CMA that, while the time required to obtain a UK MA is variable, the process can be quicker for a product that already has an MA in another European country;[33]

(b) A third party told the CMA that it would be 'easy' to get an MA in the UK by way of the 'mutual recognition' process;[34] and

(c) A Theramex internal document considering the regulatory process for relaunching Duphaston in the UK post-Merger states that 'no concerns are envisaged'.[35]

50. Taking into account the evidence above, the CMA considers that, absent the Merger, alternative purchasers would have had strong incentives to relaunch Duphaston in the UK. The Rights include the European MAs for Duphaston, and access to these MAs may facilitate the rapid reintroduction of Duphaston in the UK by an acquirer (whether by utilising the 'mutual recognition' process or otherwise benefitting from access to relevant information and clinical data).

51. With respect to [✂] specifically, the evidence reviewed by the CMA indicates that [✂] would have an incentive to relaunch Duphaston in the UK if it had acquired the Rights. The CMA has seen evidence that Duphaston was complementary to its existing portfolio in the UK.[36] In addition, since the Merger was announced, [✂].

52. Therefore, the CMA considers it realistic that, absent the Merger, Viatris would have sold Duphaston to [✂] a or an alternative purchaser. It is also realistic that [✂] or an alternative purchaser would have subsequently relaunched Duphaston in the UK.

[33] Submission to the CMA by a third party, 30 January 2024, question 5.
[34] Note of a call with a third party, paragraph 11(b), January 2024.
[35] Annex LL00017006 to the Parties' response to s109 1, October 2023, page 8.
[36] Note of a call with a third party, January 2024, paragraph 12. Third-party submission to the CMA, January 2024, question 1(b).

5. LIKELIHOOD OF GENERIC ENTRY BY THERAMEX/ [✂]

5.1.1.1.1 The [✂] Agreement

53. Theramex and [✂] - which specialises in the development of pharmaceutical products - entered into a [✂] agreement in relation to a generic dydrogesterone product on [✂] (the [✂] **Agreement**). Under the [✂] Agreement, [✂] would develop a generic dydrogesterone tablet equivalent to the originator product, Duphaston. An affiliate of [✂] would [✂] the product, and Theramex would have the right to commercialise it.[37]

54. Under the [✂] Agreement, [✂] was required to produce a dossier. A dossier includes quality data from the development of the product and is required to apply for a marketing authorisation.

55. The [✂] Agreement as made in [✂] contained provisions that allowed Theramex to terminate the agreement [✂][38] The agreement also allowed Theramex to terminate the agreement following [✂].

56. The CMA understands from Theramex that by [✂] it became apparent that there would be a delay to the original deadline for completing the dossier needed to apply for [✂]. Theramex also submitted that in December 2022, [✂] informed Theramex of the [✂] and Theramex [✂] to the contract on [✂] which included a requirement that [✂] should use reasonable efforts to [✂] by [✂].

57. The [✂] Agreement was terminated by Theramex on [✂] .[39] By this time, the generic dydrogesterone product developed by [✂] was [✂].

5.1.1.1.2 Likelihood that Theramex would have terminated the [✂] Agreement absent the Merger

58. Theramex pointed to three main reasons for its termination of the [✂] Agreement: (i) concerns regarding the [✂] for the generic dydrogesterone product including the [✂][40] (ii) an [✂] in Theramex's [✂];[41] and (iii) the fact that negotiations with

[37] Theramex Internal Document submitted to the CMA on 8 February 2024, [✂]; and Parties' submission in response to the CMA's RFI 2, 19 December 2023, paragraph 61.
[38] Theramex Internal Document submitted to the CMA on 8 February 2024, [✂].
[39] Theramex Internal Document submitted to the CMA on 8 February 2024, [✂].
[40] Parties' submission in response to the CMA's RFI 2, question 8(e), para 73.
[41] [✂].

[✂] were ongoing and [✂] considered the Duphaston rights provided a better opportunity [✂].[42]

59. Notwithstanding point (iii) above, Theramex also stated that it terminated the [✂] Agreement for reasons unrelated to the Merger. Theramex submitted that the timing of the termination of the [✂] Agreement [✂] was unrelated to the Merger. Theramex stated that this timing was driven by contractual arrangements, [✂]. Theramex further submitted that at the time that the [✂] Agreement was terminated, the purchase of Duphaston remained uncertain.

60. Had it not been for [✂] over the [✂], Theramex submitted that it would have sought to renegotiate the [✂] in the [✂] Agreement, which would have allowed it [✂].[43]

61. However, the CMA has seen evidence that the Merger was the key factor in Theramex's decision to terminate the [✂] Agreement. For example, one internal document shows that already in Spring 2023, Theramex assessed the [✂] contract,[44] and another one considers the legal implications of terminating the [✂] contract if it [✂].[45] Another internal document from July 2023 indicates that Theramex intended to terminate or modify the [✂] Agreement to [✂].[46]

62. Internal documents further suggest it was not clear that the [✂] would lead to a termination of arrangements between Theramex and [✂] in general. On [✂], Theramex's [✂] (a product not relating to HRT). The email also indicates that [✂].'[47]

5.1.1.1.3 Likelihood that Theramex would have introduced a generic dydrogesterone product into the UK if the [✂] Agreement had continued

63. Theramex stated that it would not have launched a generic dydrogesterone in the UK in the near future had its partnership with [✂] continued. The product being developed with [✂] was not envisaged to [✂].[48]

64. However, Theramex's internal documents show that it intended to launch [✂] generic dydrogesterone product in the UK. For example, two internal documents

[42] Parties' submission in response to the CMA's RFI 2, 19 December 2023, paragraph 73.
[43] Parties' response to Issues Letter, paragraph 46.
[44] Annex LL00014969 of Theramex's response to s109 1, slide 15.
[45] Annex Q9-003 to the FMN, slides 11 and 19.
[46] Theramex's Internal Document, Annex LL00030117 submitted to the CMA in response to s109 3.
[47] Theramex's Internal Document, Annex LL00030120 submitted to the CMA in response to s109 3.
[48] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 43.

refer specifically to a [✂].[49] Another internal document shows that Theramex had [✂] for generic dydrogesterone.[50] Further, an internal presentation on the Merger refers to a [✂] generic dydrogesterone [✂] by [✂], with the [✂] for the product and a part of the generic dydrogesterone [✂].[51]

65. Further, the [✂] Agreement itself identified certain countries as [✂]. Under the [✂] Agreement, Theramex was obliged to [✂].[52] The [✂] Agreement included the UK [✂] in which Theramex was [✂]. The [✂] Agreement specifically indicates that the Parties forecast sales of [✂] in the [✂].[53]

5.1.1.2 CMA assessment

66. The CMA considers that the [✂] Agreement and Theramex's internal documents show that Theramex had a [✂] in partnership with [✂]. Theramex's internal documents suggest that, absent the Merger, it would [✂] and would not have [✂]. While Theramex appeared to have some [✂], the evidence indicates that, as late as June 2023, Theramex was considering whether the [✂] partnership could [✂]. The CMA has also seen evidence that the wider commercial [✂] continued for other products, [✂] as submitted by the Parties.

67. While the Parties submitted that 'had there not been [✂] and [✂] for [✂], Theramex would simply have [✂],' the CMA considers that this in any event would have resulted in both these products being under common ownership rather than competing with each other in the market. It is also not clear whether the Merged Entity would have had the incentive to launch two bioequivalent products in the market.

68. Further, although Theramex submitted that [✂] by [✂] also contributed [✂], the CMA notes that this decision was made in [✂], and under the terms of the [✂] Agreement, [✂] could have [✂].

69. As for the timing of the planned entry, Theramex's internal documents mentioned in paragraph 64 above referred to [✂]. On this basis, the CMA considers that the entry would have been expected to take place [✂].

[49] LL00028158, slides 12, 14; and LL00017558, p.10.
[50] LL00028957, slide 19.
[51] Case ME7073_23_Merger Notice_Q9_003.pdf, slides 12, 19
[52] Theramex Internal Document submitted to the CMA on 8 February 2024, [✂].
[53] Theramex Internal Document submitted to the CMA on 8 February 2024, [✂].

70. Based on the evidence above, the CMA considers there is a realistic prospect that, absent the Merger, Theramex would have entered the UK market for dydrogesterone products in partnership with [✂].

5.1.2 Conclusion on counterfactual

71. As noted above, in phase 1 investigations, if the CMA must consider multiple potential counterfactual scenarios where each of those scenarios is a realistic prospect, it will choose the one where the merger firms exert the strongest competitive constraint on each other, and where third parties exert the weakest competitive constraints on the merger firms.[54]

72. The CMA therefore considers the relevant counterfactual to be:

(a) In relation to Femoston: the continued supply of Femoston in the UK by [✂] or another purchaser;

(b) In relation to dydrogesterone:

(a) the relaunch of Duphaston in the UK by [✂] or another purchaser; and

(b) the launch of a generic dydrogesterone product in the UK by Theramex in partnership with [✂].

6. COMPETITIVE ASSESSMENT

6.1 Background and nature of competition

73. This section provides a short overview of the structure of supply in the pharmaceutical sector, including: (i) a brief outline of the lifecycle of a medicine; (ii) the regulatory framework; (iii) the competitive dynamics for branded and generic medicines; (iv) treatments for menopause symptoms, including the marketed treatments available to patients in the UK and the activities of the Parties; and (v) the main parameters of competition.

6.1.1 Supply in the pharmaceutical sector

6.1.1.1 Lifecycle of a medicine

74. There are three main phases to the lifecycle of a drug: (i) the Research and Development (**R&D**) phase up to market launch; (ii) the period between launch and loss of exclusivity (patent expiry); and (iii) the period following the loss of

[54] CMA129, paragraph 3.12.

exclusivity, when generic products can enter the market.[55] The large majority of systemic HRT products sold in the UK are off-patent, but have not had generic entry against them to date.

75. The Parties are both active in the marketing and sale of branded and generic medicines that have already been developed, ie medicines in the second and third phase of the lifecycle. Further, the CMA considers that, while not having its own R&D in-house capabilities, Theramex is also active in the first phase of the product lifecycle in that it actively takes steps to introduce new products to the UK market. The CMA understands that Theramex either (i) acquires the rights of an existing product that was already being sold in a jurisdiction, (ii) obtains an exclusive license to market and sell a product developed by another supplier in a new jurisdiction; or (iii) partners with a third-party manufacturer to develop a generic version of an originator product.

6.1.1.2 Regulatory licensing approvals

76. Where a product has not been sold in the UK before, new entrants need to apply to the MHRA for an MA before the product is permitted to be marketed. An MA will only be granted if the MHRA concludes that the pharmaceutical product concerned shows satisfactory safety, quality and efficacy in treating the disorder(s) for which it is intended. It can take approximately two years to obtain an MA in the UK.[56]

6.1.1.3 Overview of the regulatory pricing framework

77. Once a UK MA has been obtained and before medicines are made available for patient use, the price of the product must be set and the products must be accepted by DHSC and ICBs. The regulatory framework governing the pricing of pharmaceutical sector in the UK includes voluntary and statutory schemes for branded and generic medicines.

78. There are two pricing arrangements for branded medicines: (i) the 2024 Voluntary Scheme for Branded Medicines Pricing, Access and Growth (**VPAG**);[57] and (ii) the Statutory Scheme.[58] The VPAG is a voluntary agreement between DHSC, the NHS and the Association of the British Pharmaceutical Industry. It contains a number of provisions that create direct or indirect restrictions on the pricing of branded medicines in the UK, including, among other things, the requirement for

[55] These phases are discussed by the Association of the British Pharmaceutical Industry (https://www.abpi.org.uk/value-and-access/uk-medicine-pricing/medicine-lifecycle/, accessed 6 March 2024) and by the European Commission in its Pharmaceutical Sector Inquiry, EC: 'Pharmaceutical Sector Inquiry Report' (https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf accessed 6 March 2024).
[56] Submission to the CMA from a third party, January 2024, question 2.
[57] The scheme is applicable to all branded medicines, including branded generics (ie generic drugs that have been given a proprietary market name) and whether or not they are patent protected.
[58] The 2024 VPAG came into effect on 1 January 2024, following expiry of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (**VPAS**) and shall remain in force for a period of five years (until 31 December 2029).

DHSC to approve the price of new products and price changes to existing products. It also includes arrangements to control scheme members' profits at a portfolio level. The Statutory Scheme covers pharmaceutical companies that have not opted into the VPAG and aims to operate in a similar way. [59]

79. Suppliers of generic medicines are required to provide pricing and sales information to DHSC under the Health Service Products (Provision and Disclosure of Information) Regulations 2018 (the **Regulations**). Unlike VPAG, the Regulations do not impose direct controls over the price that a manufacturer may charge for its generic products. Suppliers may set or alter the price at which the medicine is sold to wholesalers or pharmacies at any time according to market conditions.[60]

6.1.1.4 The Drug Tariff and reimbursement

80. The reimbursement for dispensing medicines in the UK is regulated under Part VIII of the NHS Drug Tariff. When a dispensary (eg a pharmacy) supplies a product listed under Part VIII of the Drug Tariff, it is reimbursed by the NHS according to the price listed in the Drug Tariff.[61] It categorises medicines as follows:

    (a) Category A medicines, which include generic products that are widely available but that involve smaller markets. The reimbursement price of these is based on a weighted average list of prices from wholesalers and generic manufacturers.

    (b) Category C products include medicines that are not readily available as a generic. The reimbursement price of this category is based on NHS List Price, which is in turn set under the VPAG, as discussed in paragraph 78 above.

    (c) Category M medicines, which are readily available as generics. DHSC calculates a reimbursement price based on manufacturer data.

81. HRT products like Bijuve, Femoston Sequi, Femoston Conti are classified as Category C. For these medicines, the dispensing pharmacist will be reimbursed the NHS List Price set by DHSC.

6.1.1.5 Prescribing by clinicians

82. In the UK, systemic HRT is available on prescription by clinicians. The majority of patients will be prescribed HRT following a consultation with their GP, although in

[59] Set up under sections 262-264 National Health Service Act 2006, and set out in the Branded Health Service Medicines (Costs) Regulations 2018 (SI 2018/345).
[60] Note of call with a third party, January 2024, paragraph 5.
[61] In practice there is a percentage discount applied on the basis that pharmacies will be able to negotiate a discount with suppliers. Note of a call with a third party, January 2024, paragraph 7.

complex cases a patient may be referred to a menopause specialist GP or gynaecologist.[62] In such cases, the gynaecologist will usually write the initial prescription and, once the patient is settled on the treatment, the GP will provide repeat prescriptions.[63]

83. The clinician will write a prescription for the particular product(s) they have selected for a pharmacist to dispense. When generics are not readily available, the prescription will state the particular brand name of the product(s) and the pharmacist will have to dispense that exact branded product. For generic products (especially in the case of oral products), the prescription will typically specify the molecule(s) to be dispensed and the pharmacist will choose between the set of products based on that molecule(s).[64]

84. In the next section, the CMA considers how the pricing framework and clinical decision-making described above impacts the competitive dynamics between suppliers of branded and generic medicines.

6.1.2 Competitive dynamics for branded and generic medicines

85. This section considers the competitive dynamics and the resulting parameters of competition by which suppliers compete to supply systemic HRT treatments. The CMA considers the parameters relevant for the supply of branded and generic products separately.

6.1.2.1 Branded medicines

86. When only a branded version of a medicine is available, pharmaceutical companies of therapeutically substitutable medicines compete with each other to influence clinical prescribing behaviour. This is achieved through marketing expenditure aimed at increasing awareness of approved indications, effectiveness and side effects of their drugs. As discussed in paragraph 82, GPs are the primary prescribers of systemic HRT products.[65] The CMA understands that HRT suppliers' promotion efforts typically target a range of stakeholders including clinicians, 'key opinion leaders' and organisations such as the BMS, which in turn, influence the wider GP population.[66]

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[62] See Overview - British Menopause Society (thebms.org.uk). The majority of GPs in the UK are not menopause specialists.
[63] Note of a call with a third party, January 2024, paragraph 12.
[64] Note of a call with a third party, January 2024, paragraph 22.
[65] Note of a call with a third party, November 2023, paragraph 10. Secondary care clinicians, principally gynaecologists, also prescribe systemic HRT in hospital settings. Once the first prescription is written in hospital, it is transferred back to the patient's GP and, as such, is ultimately very similar to prescriptions first written by a GP. Note of a call with a third party, November 2023, paragraph 12.
[66] Note of a call with a third party, January 2024, paragraph 29. Note of a call with a third party, November 2023, paragraphs 3 and 19-21. Note of a call with a third party, November 2023, paragraph 8. Note of a call with a third party, November 2023, paragraph 19-21. Note of a call with a third party, January 2024, paragraphs 22-23 and 27-30.

87. Suppliers will also compete to influence commissioning bodies such as the ICBs, as medicines typically have to be accepted onto individual NHS local areas' formularies before they are prescribed by a clinician.[67] ICBs can also guide clinical decision-making by directing clinicians to consider prescribing some products before others. The CMA found evidence that some, but not all, local areas guide clinicians to use particular products, for example by using prescribing software which requires clinicians to prescribe HRT products in a particular order.[68]

88. Systemic HRT is characterised by significant switching costs, in particular because patients/clinicians are reluctant to switch when they are stable on their treatment.[69, 70] Patients will change treatments from sequential HRT to continuous HRT as they move through the different stages of the menopause.[71] In practice, HRT suppliers have an incentive to compete not only for new patients needing HRT treatments but also for patients who transition from perimenopause to postmenopause.

89. As well as maximising the reach of their existing portfolios, suppliers have an incentive to improve their existing products and to expand their product range to win new patients. This is likely to become more important as the demand for systemic HRT continues to increase in the UK.

90. The Parties submitted that the parameters by which various HRT treatments competed were determined by the clinical needs of patients, which in turn, would drive clinical decision-making.[72] This is consistent with the evidence that the CMA received from third parties, ie the choice of treatments was largely influenced by a patient's medical needs. Clinicians are more likely to prescribe higher quality products, ie those products they consider to more safely and effectively meet a patient's particular clinical needs compared to alternative treatments.[73]

91. In addition to these clinical factors, competitors identified security of supply as the most important parameter of competition, followed by engagement with clinicians

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[67] Applications to the committees are made by a clinician practising in that local area. Suppliers promote their products to clinicians by providing a 'formulary pack' and clinical data on the product. Formulary committees consider a product's effectiveness and safety as well as its cost implications for their budgets, ie the product's NHS price.
[68] Note of call with a third party, January 2024, paragraphs 23 and 25. Note of a call with a third party, January 2024, paragraph 32. Note of a call with a third party, November 2023, paragraphs 25-26; Note of a call with a third party, November 2023, paragraph 23.
[69] Note of a call with a third party, November 2023, paragraph 26.
[70] Other exceptions identified to the CMA include: temporarily switching in response to a product shortage (Note of a call with a third party, January 2024, paragraphs 26-27); patients continuing to take HRT over the age of 60 potentially switching from oral to transdermal products (Note of a call with a third party, November 2023, paragraph 17); or if the patient develops risk factors over time which requires them to switch from an oral to a transdermal product (FMN, paragraph 99).
[71] FMN, paragraph 96.
[72] FMN 169.
[73] Clinicians and the Parties consistently identified those products they considered to be safest and most effective for patients as the superior prescribing options (for example, Note of a call with a third party, November 2023, paragraphs 8-9 and Note of a call with a third party, paragraphs 9-10 and 19-21; FMN, Table 4 and paragraphs 110-114). Additionally, the Parties told the CMA that suppliers looked to use clinical trials to improve their products in ways which improve patient safety or efficacy (FMN, paragraph 207(ii)).

and formularies and the marketing of products. Price was considered as the fourth most important parameter of competition. It was followed by the breadth of a supplier's product range and their development of new products.[74]

92. Clinicians identified that price was a factor for formularies in deciding whether to list products.[75] Additionally, clinicians and formularies indicated that some, but not all, formularies ranked their listed products in a way that encouraged clinicians to prescribe lower-priced products as the first line treatment where they were medically suitable.[76]

93. Based on the evidence received, the CMA considers that competition for the supply of systemic HRT likely takes place across several parameters, including:

(a) Product quality, namely its efficacy and safety for different patient types relative to alternative products;

(b) Promotion and marketing efforts to prescribing clinicians and local area formulary committees;[77]

(c) Product range development, including further developing existing products;

(d) Price, when negotiating with DHSC and when applying to local area formulary committees; and

(e) Security of supply.

6.1.2.2 Generic medicines

94. Many of the current HRT branded products are off-patent, including some which have been off-patent for several decades, and so are entering or have entered the third stage of the drug lifecycle. At this point, there may be entry of therapeutically equivalent generic versions of the originator product.

95. The Parties submitted that there was ongoing development of generic products that would compete with the branded products on the market and gave an example of a branded generic micronised progesterone, Gepretix, which is a recent entrant.[78] However, as set out in section 6, beyond progestogen-only products, there has been no other generic entry to date and nor is such entry

[74] The CMA asked competitors to list and rank the most important competitive factors in the supply of systemic HRT in the UK. Response to the CMA questionnaire from a number of competitors, February 2024, question 6.
[75] Note from a call with a third party, November 2023, paragraph 19.
[76] Note of a call with a third party, January 2024, paragraph 30. Note of a call with a third party, November 2023, paragraph 25. Note of a call with a third party, January 2024, paragraph 24. Responses to the CMA questionnaire from a third party, February 2024, question 8. Note of a call with a third party, November 2023, paragraph 25.
[77] Whilst the Parties cannot actively market to patients, the CMA has seen evidence that Theramex also funds patient education efforts as a way to encourage 'upwards pressure' from patients on their clinicians to prescribe HRT. The CMA understands that this was a central element of Theramex's strategy to promote its Evorel products. Theramex' Internal Document, Annex LL00000973 of the response to s109 1, slides 27 and 53.
[78] FMN, paragraph 226.

expected in the foreseeable future, including in relation to Theramex's off-patent HRT products or Femoston.

96. Once a generic product is available, clinicians are encouraged to prescribe generically, and pharmacies are free to dispense the relevant generic version or originator product. The NHS reimbursement system provides incentives for pharmacies to prescribe cheaper drugs, and also to negotiate lower prices with the manufacturers to further benefit from the set reimbursement price. Accordingly, the first generic entrant would seek to lower its price to incentivise pharmacies to stock its product alongside the branded product and seek to win volumes and market share. Subsequent generic entrants would also have the same incentives. A supplier told the CMA that negotiating a price with DHSC substantially below the price of the originator product made it easier to be listed on local formularies and subsequently dispensed by pharmacies.[79]

97. As such, after generic entry, the competitive dynamics between the originator supplier and generic suppliers, and between generic suppliers if there is more than one, are to a large extent driven by price. The CMA has found in past cases that the number of generic manufacturers would impact the intensity of that price competition, and further generic entry would be expected to lead to a downward impact on price.[80] Therefore, the CMA considers that, in the case of generics, the key parameter of competition is price.

6.1.3 Treatments for menopause symptoms

98. Menopause is when a patient's periods stop due to lower hormone levels. It usually affects patients between the ages of 45 and 55 but can happen earlier. Perimenopause is when the patient has symptoms of menopause, but their periods have not stopped. Perimenopause ends, and postmenopause begins, 12 months after the patient's last period.[81] Menopause can cause symptoms like anxiety, mood swings, brain fog and hot flushes. These symptoms can start years before a patient's periods have stopped and can carry on afterwards.[82]

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[79] Note of call with a third party, January 2024, paragraph 20.
[80] The CMA's decision, 'Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK' case 50395, July 2021, (https://assets.publishing.service.gov.uk/media/61b8755de90e07043f2b98ff/Case_50395_-_Decision_final___.pdf) accessed on 7 March 2024. The CMA's findings are consistent with results obtained in academic literature – for example, Olson and Wendling (2018) find, from an analysis of US data, that the entry of a third competitor (in addition to the original incumbent) has a statistically significant negative impact on price, even in small markets (Olson, L. M., & Wendling, B. W. (2018). Estimating the causal effect of entry on generic drug prices using Hatch–Waxman exclusivity. Review of Industrial Organization, 53(1), 139-172). Grandlund and Bergman (2018), using data from Sweden, find that the effect of the number of firms on prices is well described by constant elasticities; this means that, for example, the percentage effect on generic prices of going from six to nine firms is almost the same as that of going from two to three firms (Granlund, D., & Bergman, M. A. (2018). Price competition in pharmaceuticals–evidence from Swedish markets. Journal of health economics, 61, 1-12).
[81] In practice the distinction between perimenopause and menopause may not be clear cut.
[82] NHS website, 'Menopause' (May 2022), (Menopause - NHS (www.nhs.uk)) accessed on 7 March 2024.

6.1.3.1 Marketed treatments for menopause symptoms

99. Systemic HRT is the most commonly used treatment for managing menopausal symptoms. The main component of HRT is the hormone oestrogen.[83, 84] This can be given in the form of oral tablets or delivered through the skin (transdermally) in the form of patches, gels or sprays. Giving oestrogen through the skin is preferred for patients at increased risk of blood clots.[85] Patients who have had a hysterectomy take oestrogen-only HRT.

100. Progestogen is typically given to patients who have not had a hysterectomy, to protect the lining of the womb from the effect of oestrogen.[86] Progestogens come in the form of natural micronised progesterone tablets or as synthetic progestogens. [87, 88]

101. Perimenopausal patients most often receive sequential progestogen treatment, where they take oestrogen for the full menstrual cycle and progestogen for only half the cycle. There are products that contain oestrogen and progestogen in a single dose (combined products), or where appropriate patients/clinicians may opt to take the oestrogen and progestogen products separately. Postmenopausal patients generally take continuous HRT, meaning that both oestrogen and progestogen are taken every day. As above, patients/clinicians can choose whether to use combined or separate treatments. NHS guidance states that patients usually require treatment for two to five years, although in some cases this will be longer.[89]

102. Demand for systemic HRT has increased significantly since NICE updated its guidance on menopause and systemic HRT in 2015. In recent years, there have been supply shortages of multiple systemic HRT products, due to a combination of increased demand and a number of supply-side factors.[90] The CMA considers the increased demand for HRT and supply shortages in more detail in the competition assessment.

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[83] FMN, paragraph 6.
[84] Systemic HRT can be complemented, but not replaced, by taking local topical HRT products which treat localised symptoms of menopause (Note of a call with a third party, November 2023, paragraph 31 and FMN, paragraph 120). As such, the CMA considers that local HRT products are not relevant to identifying product overlaps between the Parties and would pose no competitive constraint on the Merged Entity.
[85] There are various reasons why a patient may be at increased risk of blood clots, such as raised body mass index, raised blood pressure, smoking and family history. As such, a significant proportion of patients will be at increased risk.
[86] Theramex submitted that around 20% of women have had a hysterectomy by age 55 (FMN, footnote 29).
[87] Micronised progesterone is plant derived and is similar to the chemical structure of progesterone produced by the human ovaries (body-identical). (Effectiveness of transdermal oestradiol and natural micronised progesterone for menopausal symptoms - PMC (nih.gov) , accessed 6 March 2024).
[88] Synthetic progestogens are available in the form of oral tablets, patches (in combination products) or in the form of the intrauterine progestogen releasing system (Mirena IUS). The Mirena IUS has a tertiary indication for endometrial protection.
[89] NHS website, 'When to take hormone replacement therapy' (January 2023) (When to take hormone replacement therapy (HRT) - NHS (www.nhs.uk)) accessed on 6 March 2024.
[90] Joint BMS, FSRH, RCGP and RCOG position statement on the supply shortages of Hormone Replacement Therapy (HRT) accessed 6 March 2024.

6.1.3.2 The Parties' systemic HRT activities

103. Theramex offers a broad portfolio of systemic HRT products containing combined treatments that can be taken orally and transdermally.[91] Theramex also offers oestrogen-only options for patients who prefer separate treatments.

104. Theramex has no R&D capabilities. Instead, if it wishes to develop and/or introduce a new product (or a new version of an existing product), it does so by acquisition or in-licensing,[92] or by contracting a third-party developer.[93]

105. Viatris submitted that it was divesting the majority of its women's healthcare business.[94] This comprises the Rights (which it intends to sell to Theramex), its Elleste range (which has been sold to Insud Pharma) and Zumenon and Cyclo Progynova, which are not being sold. Cyclo Progynova was discontinued in 2017.

6.1.3.3 Development of product range

106. As explained in section 6.1.2.1, product range development is one of the parameters of competition by which HRT suppliers compete.

107. The evidence indicates that HRT suppliers have developed and introduced innovations to their product range. Theramex, although it does not have its own R&D capabilities, has developed its product range, with recent examples including:

(a) Theramex's redevelopment of the [✂];

(b) The licensing of Bijuve's 1mg oestrogen dosage version to the UK;

(c) Theramex's planned UK commercialisation of the [✂] product it currently sells in other countries;

(d) Theramex's contracts with pharmaceutical product development companies, to develop generic versions of existing systemic HRT products, such as [✂] to develop [✂].

108. Examples of product range developments from other HRT suppliers include Gedeon Richter, which introduced its Lenzetto Spray in 2022, and Exeltis, which introduced Gepretix, a generic version of Utrogestan.[95]

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[91] FMN, paragraph 58. Theramex also offers several other products to treat the symptoms of menopause which are not systemic HRT and therefore are not relevant to the Merger (FMN, paragraph 59).
[92] FMN, paragraph 196.
[93] Parties' teach-in slide deck, 18 January 2024, slide 25.
[94] Parties' submission in response to the CMA's request for information (**RFI 1)**, 11 November 2023, paragraph 2.
[95] Submission to the CMA from a third-party, January 2024.

6.2 Theories of harm

109. The CMA assesses the potential competitive effects of mergers by reference to theories of harm. Theories of harm provide a framework for assessing the effects of a merger and whether or not it could lead to an SLC relative to the counterfactual.[96]

110. In its investigation of this Merger, the CMA considered the following theories of harm:

(a) horizontal unilateral effects arising from the loss of competition in the supply of systemic HRT in the UK; and

(b) horizontal unilateral effects arising from the loss of future competition in the supply of dydrogesterone in the UK.

111. Each of these theories of harm is considered below.

6.3 Horizontal unilateral effects in the supply of systemic HRT in the UK

6.3.1 Market definition

112. Where the CMA makes an SLC finding, this must be 'within any market or markets in the United Kingdom for goods or services'. An SLC can affect the whole or part of a market or markets. Within that context, the assessment of the relevant market(s) is an analytical tool that forms part of the analysis of the competitive effects of the merger and should not be viewed as a separate exercise.[97]

113. Market definition involves identifying the most significant competitive alternatives available to customers of the merger parties and includes the sources of competition to the merger parties that are the immediate determinants of the effects of the merger.

114. While market definition can be an important part of the overall merger assessment process, the CMA's experience is that in most mergers, the evidence gathered as part of the competitive assessment, which will assess the potentially significant constraints on the merger parties' behaviour, captures the competitive dynamics more fully than formal market definition.[98]

[96] CMA129, paragraph 2.11.
[97] CMA129, paragraph 9.1.
[98] CMA129, paragraph 9.2.

6.3.1.1 Product market

115. The CMA considers that in cases involving differentiated products, such as this one, there is often no 'bright line' that can or should be drawn. Rather, it can be more helpful to describe the constraint posed by different categories of products or suppliers as sitting on a continuum between 'strong' and 'weak'.

116. The Parties overlap in the supply of systemic HRT products. Theramex offers a portfolio of products that includes continuous and sequential treatments, oral and transdermal products, and separate and combined products. Femoston offers continuous and sequential treatments in oral combined products only.

117. The Parties submitted that HRT products are differentiated but that all products form part of a wide HRT market.[99]

118. The evidence received by the CMA indicates that differences between the products relate mainly to the mode of application, the chemical composition of the product and whether the treatments are taken sequentially or continuously. The CMA considered the degree of substitutability between systemic HRT products by reference to these factors below.[100]

6.3.1.2 Modes of application (oral and transdermal products)

119. The Parties submitted that oral and transdermal products are very distinct and there is no demand-side substitution for patients who have risk factors, and those patients would only be able to take transdermal products.[101] The Parties further submitted that guidance documents from NICE, BMS and DHSC also demonstrate that products with different modes of application are not substitutable for each other.[102]

120. The evidence gathered by the CMA indicated that the choice of a mode of application can be influenced by clinical factors and by patient preference.

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[99] Parties' response to Issues Letter, paragraphs 7-9 and pages 28-31.
[100] Some third parties identified products that were not systemic HRT that could be used to treat the symptoms of menopause as alternatives to systemic HRT products (Response to the CMA questionnaire from a number of third-parties, February 2024, question 7). Tibolone, which is a steroid, was identified most frequently as an alternative to systemic HRT. However, some clinicians indicated there was low awareness among GPs of Tibolone as a treatment option for patients suffering from menopause symptoms. Furthermore, the Parties submitted that they did not consider Tibolone to be within the same market as systemic HRT (Parties' submission in response to the CMA's request for information 3 **(RFI 3)**, 24 January 2024, paragraph 48.) and therefore Tibolone has not been included in the relevant product market. Beyond Tibolone, some other products identified to the CMA by clinicians included a subdermally-inserted 'pellet' (Note of a call with a third party, November 2023) and NK3 inhibitors (Note of a call with a third party, November 2023, paragraph 30). However, these products were noted by only one clinician and/or were identified as being only used for niche types of patient, such as those for whom systemic HRT is not effective or who have hormone-dependent cancers. Therefore, the CMA did not consider them further.
[101] Parties' response to Issues Letter, page 28-29.
[102] Parties' Response to Issues Letter, paragraph 19(a); Parties' Presentation at Issues Meeting, Slide 10.

121. The evidence indicated that, from a clinical perspective, oral and transdermal products are largely substitutable, except for a sub-set of patients with risk factors that make oral products unsuitable.

122. Third parties told the CMA that a patient's clinical need is an important factor in choosing a suitable HRT product. Third party evidence, in particular from clinicians, further indicated that, for the majority of patients with no oral risk factors,[103] there is no major medical difference between oral or transdermal HRT products. For example, one formulary considered all systemic HRT products are viable alternatives, noting the degree of substitutability between oral and transdermal treatments. The choice is largely for the patient and/or clinician to make.

123. NICE's clinical guidance stated that HRT is available as oral or transdermal preparations, depending on the patient's preference. However, the Guidelines also specified that transdermal preparations may be appropriate for patients with certain risk factors.[104] Similarly, the BMS Guidance from January 2024 presented both oral and transdermal products as viable options, except in the case of patients with certain risk factors who should be prescribed transdermal products.[105]

124. The CMA also considered the Parties' statement that marketing efforts of suppliers influenced preferences from clinicians and patients. The CMA notes that preferences for transdermal products have contributed to their growth in popularity relative to oral products (although both product types grew in the last three years). Suppliers' promotion efforts, specifically by those who supply transdermal products like Theramex, may be one driver of this shift. While this indicates that patients may increasingly prefer one product type over the other, the CMA considers that this trend does not show that oral and transdermal HRT products are not substitutable to one another generally.

125. Based on the evidence above, the CMA considers that oral and transdermal products are in the same product market for patients with no oral risk factors and the CMA will take into account any differentiation between those product types in its competitive assessment.

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[103] See paragraph 999999. Competitors also indicated that all systemic HRT products generally competed against each other, but a few competitors differed on the degree of substitutability between the different product types in particular as regards oral versus transdermal products. One competitor told the CMA that oral and transdermal products were reasonably substitutable for each other and noted that how shortages in one increased demand for the other. It also noted that the use of oral products was declining due to some patients preferring transdermal products due to the perception of them as safer (Note of a call with a third party, January 2024, paragraph 40-41) However, another competitor told the CMA that it did not compete against Femoston Conti because it does not offer an oral product, suggesting it viewed oral and transdermal products as not competing against each other (Note of a call with a third party, December 2023, paragraph 15).

[104] Hormone replacement therapy (HRT) | Prescribing information | Menopause | CKS | NICE

[105] 04-BMS-TfC-HRT-Guide-NOV2022-A.pdf (thebms.org.uk), p.2 (last accessed 22nd March 2024).

6.3.1.3 Combined and separate products

126. The Parties submitted that there is no clinical difference between fixed dose HRT combinations and individual components.[106]

127. Third parties, in particular healthcare professionals, told the CMA that separate products have the advantage of being more adjustable for an individualised treatment. On the other hand, health care professionals also said that combined products are better for patient compliance, ie ensuring that patients take the correct dosages consistently.[107] Competitors were of the opinion that combined and separate products compete with another.[108] The evidence shows that there is some competitive interaction between combined and separate HRT products.

128. For patients taking both oestrogen and progestogen, BMS guidance generally listed both separate and combined products as suitable. [109] The NICE Guidelines did not specify whether separate HRT products are interchangeable with the combined fixed dose treatments.

129. Based on the evidence above, the CMA considers that separate and combined products are in the same product market, but it notes that for some groups of patients it may be preferable to take combined products, whereas for others it may be preferable to take separate products, and the CMA will take this differentiation into account in the competitive assessment.

6.3.1.4 Sequential and continuous treatments

130. The Parties submitted that there is no clear distinction between treatments for perimenopausal and postmenopausal patients, and that it is not always the case that sequential treatments are prescribed for perimenopausal patients and continuous treatments are prescribed for postmenopausal patients. The Parties also noted that patients who are stable on one product during perimenopause often preferred to continue with that product during postmenopause.[110]

131. The CMA considers that for patients who take progestogens for every day of the menstrual cycle (ie continuously), either a continuous combined product or separate products can be taken; and that for patients who take progestogen for only half of the cycle (ie sequentially), either a sequential combined product or separate products are suitable.

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[106] Parties' response to Issues Letter, paragraph 8.
[107] There can be risks for patients not taking the prescribed progestogen part of the treatment and potentially costs for the NHS: when a patient misses doses of progestogen this can lead to bleeding, which must then be investigated to rule out serious causes such as cancer. Note of call with a third party, November 2023, paragraph 24.
[108] Note of a call with a third party, December 2023, paragraph 6 and Note of a call with a third party, January 2024, paragraph 36-38.
[109] 04-BMS-TfC-HRT-Guide-NOV2022-A.pdf (thebms.org.uk), p.2 (last accessed 22nd March 2024).
[110] Parties' response to Issues Letter, para 8 and page 28.

132. Third-party evidence indicated that some clinicians have a preference to prescribe sequential treatments for perimenopausal patients and continuous treatments for postmenopausal patients. However, other clinicians preferred the same products for both types of patient.

133. BMS Guidance from January 2024 advised that, for patients who have not had a hysterectomy, clinicians should prescribe sequential treatments to perimenopausal patients and continuous treatments for postmenopausal patients.[111] The same approach is reflected in the NICE Guidance.[112]

134. Based on the evidence above, the CMA considers that sequential treatments are generally preferred for perimenopausal patients and continuous treatments are generally preferred for postmenopausal patients. However, the CMA acknowledges that there is no bright line between peri- and post- menopause and separate products, which represent a large proportion of the systemic HRT market, can be used for both. Therefore, the CMA has assessed the effects of the Merger in relation to a product market including both sequential and continuous products and has taken into account any differences between these products in its competitive assessment.

6.3.1.5 Conclusion on relevant product market

135. Based on the evidence above, the CMA considers that the different types of systemic HRT treatments set out above (oral and transdermal; combined and individual; sequential and continuous) are broadly substitutable, but that specific patients may have clinical needs or preferences that may make some forms of treatment more suitable for them. The CMA therefore considers that the relevant product market is the supply of systemic HRT but it will take into account clinical needs and preferences in the competitive assessment.

6.3.1.6 Geographic market

136. The Parties submitted that the geographic market should be national in scope due to: (i) previous CMA and European Commission decisions that defined the geographic market for pharmaceutical products as being national; (ii) the national regulatory and reimbursement systems; (iii) competition between pharmaceutical companies is predominately national and (iv) MAs are granted at the national level.[113]

137. The CMA did not receive any evidence to suggest that there are significant differences in the NHS's operations across nations that would impact the

[111] 04-BMS-TfC-HRT-Guide-NOV2022-A.pdf (thebms.org.uk), p.2 (last accessed 22nd March 2024).
[112] Hormone replacement therapy (HRT) | Prescribing information | Menopause | CKS | NICE.
[113] FMN, paragraph 140.

geographic scope of reference for its assessment of the Merger. On the basis of evidence gathered in this investigation, the CMA considers that the relevant geographic market is the UK.

6.3.1.7 Conclusion on market definition

138. Based on the evidence above, the CMA has concluded that the relevant market is the supply of systemic HRT in the UK.

6.3.2 Competition assessment

139. Horizontal unilateral effects may arise when one firm merges with a competitor that previously provided a competitive constraint, allowing the merged entity profitably to raise prices or to degrade quality on its own and without needing to coordinate with its rivals.[114] Horizontal unilateral effects are more likely when the parties to a merger are close competitors.[115]

140. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC as a result of horizontal unilateral effects in the supply of systemic HRT in the UK. The CMA has examined the closeness of competition between the Parties and the competitive constraints which would remain on the Merged Entity.

141. The CMA assessed the Merger with respect to the overall supply of systemic HRT in the UK and within particular product types where appropriate, in particular in relation to women who can use both oral and transdermal products and who have not had a hysterectomy. The CMA has considered evidence from the Parties (including submissions, internal documents and sales data) and from third-party competitors, clinical experts, local area formularies and HRT prescribing guidance. In particular, the CMA has assessed:

(a) Shares;

(b) Internal documents;

(c) Price setting negotiations with DHSC;

(d) Bijuve's commercial position;

(e) Evidence from HRT prescribing guidance; and

(f) Evidence from third parties, specifically clinicians, local area formularies and competitors.

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[114] CMA129, paragraph 4.1.
[115] CMA129, paragraph 4.8.

6.3.2.1 Shares

142. To assess the effects of the Merger, the CMA has sought to estimate shares by revenue to help understand the relative strength of different HRT products being sold in the UK.

6.3.2.1.1 Parties' submissions

143. The Parties submitted that shares have low evidential value because all systemic HRT products are highly differentiated from each other, noting in particular the differences between oral and transdermal products.[116]

6.3.2.1.2 Evidential value of shares

144. Shares can be useful evidence when assessing closeness of competition and can provide insight on the current size, strength and relative importance of suppliers and products being sold in a market. For differentiated products, or where customer preferences are diverse, such as in this case, shares may not provide evidence on the closest alternatives available to the merger firms' customers, as these may be different from the products that achieve the greatest sales across a wider body of customers. In such cases, the CMA may rely to a greater extent on other sources of evidence on closeness of competition.[117]

145. Notwithstanding the differentiated nature of HRT products, the CMA found that there was broad substitutability between all systemic HRT products (see section 6.3.1). In this light, the CMA considers that shares have evidential value as they provide a record of which HRT products have been most successful, which in turn reflects the choices made by clinicians and patients. The CMA considered shares evidence alongside other evidence types in this case, including the Parties' internal documents, third-party evidence and the CMA's formulary status analysis.

6.3.2.1.3 CMA's shares estimates

146. The CMA calculated shares using revenue data for the period between January 2020 and September 2023.[118] Shares were calculated using revenue from the MIDAS IQVIA dataset and, due to accuracy issues with this dataset, supplemented with submissions from the Parties and some third parties where

[116] Parties' response to Issues Letter, paragraphs 8-10.
[117] CMA129, paragraph 4.14 and 4.15
[118] Revenue data provided to the CMA in a currency other than GBP was converted using the yearly average exchange rate for the year the data related to.

possible.[119] The shares include all products which the CMA considers to be used for systemic HRT, except the Mirena coil.[120]

147. As discussed in paragraph 88, this market is characterised by high switching costs, in particular as patients who are stable on a product are unlikely to switch. As a result, suppliers typically compete for new patients. The dataset available to the CMA did not differentiate between new and old patients, and therefore the shares of recently launched products are likely to understate their competitive strength when competing for new patients. The CMA takes this into account when reaching its views on the impact of the Merger. The CMA provides shares estimates for

(a) All systemic HRT products;

(b) Product types separately to identify trends in the relative sizes of different product type segments; and

(c) Oral combined continuous products.

6.3.2.1.3.1 All systemic HRT

148. Table 1 sets out shares for all systemic HRT products.

Table 1: Shares for all systemic HRT (January to September 2023)

Supplier	**%**	**Value**
Theramex	[30-40%]	£[✂]
Femoston	[5-10]%	£[✂]
Combined	**[40-50]%**	£[✂]
Bayer	[0-5]%	£[0-5]m
Besins Healthcare	[30-40]%	£[40-50]m
Gedeon Richter	[0-5]%	£[0-5]m
Norgine	[0-5]%	£[0-5]m
Novartis	[0-5]%	£[0-5]m
Novo Nordisk	[0-5]%	£[0-5]m
Pfizer	[0-5]%	£[0-5]m
Viatris	[0-5]%	£[0-5]m
Other[121]	[0-5]%	£[0-5]m
Total	100%	£[110-120]m

Source: MIDAS IQVIA, Parties' submissions, third-party submissions. Theramex is the largest supplier of all systemic HRT products at [30-40]%, followed by Besins Healthcare at [30-40]%. The Merger would result in the combination

[119] IQVIA is a global provider of analytics on the healthcare industry. IQVIA tracks suppliers' revenues and volumes for the sale of pharmaceutical products in the UK (https://www.iqvia.com/about-us (accessed 7 March 2024)). IQVIA's data may underestimate or overestimate actual revenue and volumes. For example, IQVIA's estimate of Bijuve revenues was lower than Bijuve's actual revenues, which the CMA was able to confirm with Theramex.
[120] The CMA was not able to obtain data on the use of IUSs such as the Mirena coil as HRT (as opposed to contraception). The CMA notes that the Mirena coil has multiple therapeutic indications and use as HRT will represent only a proportion of its sales revenue. Therefore, IUSs are not included in the CMA's shares of supply calculations and their competitive role is considered using other evidence types, principally evidence from clinicians.
[121] Advanz Pharma, Orion, Pharmanovia, Resource Medical, Teva.

of the first and third largest competitor, with Femoston providing an increment of [5-10]%.[122] Overall, Theramex's share has increased by [10-15] percentage points since 2020, although it fell in 2023 from its peak of [40-50]% in 2022.

149. The Parties supply the most or second-most successful products in five of the six main product type segments.

(a) For combined continuous transdermal products, Theramex is the only supplier;

(b) For combined sequential transdermal products, Theramex is also the only supplier;

(c) For combined continuous oral products, Femoston Conti is the largest oral combined continuous product, with a share of [40-50]% in 2023 (see Table 2);

(d) For combined sequential oral products, Femoston Sequi is the largest product, with a share of [60-70]% in 2023; and

(e) For oestrogen-only transdermal products, Theramex's Evorel is the second-most successful product with a share of [20-30]% in 2023.

150. Besins Healthcare is the second-largest supplier and has experienced rapid growth since 2020, gaining market share of [30-40]%. However, its portfolio is narrower than Theramex's and contains only separate products, specifically one oestrogen-only product Oestrogel product and one progestogen-only product, Utrogestan. At the same time, its two products are the most successful products in their respective product types, ie Oestrogel is the largest oestrogen-only transdermal product with a share of a [40-50]% and Utrogestan is the largest product by a considerable margin with a [80-90]% share in their respective product type segments.

151. No other supplier has more than 5% share and these suppliers usually only supply products within just one or two product type segments. With the exception of relatively recent entrant Gedeon Richter, all other suppliers' shares have fallen since 2020, including Novartis' and Norgine's, which both only supply oestrogen-only transdermal products, and Novo Nordisk and Viatris, which both mainly supply oral combined products.

6.3.2.1.3.2 By product type

152. The HRT market has grown rapidly since January 2020, with total revenue increasing almost 300% (annualising 2023 revenues). Separate products'

[122] Femoston's share across all systemic HRT products has decreased since 2020 by [10-20] percentage points, in line with the general trend of transdermal products growing in popularity relative to oral products. However, Femoston Conti and Femoston Sequi remain the largest products in the combined oral continuous and sequential product type segments respectively.

revenues have grown faster than combined products', becoming larger than combined products in 2023. Also, transdermal product revenues have grown faster than oral product revenues.

153. Demand for oral combined (sequential and continuous) products has decreased by 10% since 2020, with the proportion of that segment relative to all HRT products falling from [30-40]% to [5-10]%.

154. The CMA acknowledges these trends but notes that, as the market grows and further awareness is raised among clinicians and patients, growth trajectories of specific product types may change. Accordingly, it is not possible to predict whether these trends will stay the same or change in the future, which the CMA has taken into account in its competition assessment. In addition, while demand for combined oral products has decreased, these remain significant, representing close to 10% of the market,[123] in particular having regard to the fact that combined oral products may be preferable for vulnerable patients that need to rely on a combined pill for compliance reasons.[124]

6.3.2.1.3.3 Oral combined continuous products

155. The Parties compete closely against each other within the combined continuous oral products segment. Table 2 sets out shares for oral combined continuous products.

Table 2: Shares for combined continuous oral products (January to September 2023)

Supplier	***%***	***Value***
Theramex	[0-5]%	£[✂]
Femoston	[40-50]%	£[✂]
Combined	**[40-50]%**	£[✂]
Novo Nordisk	[40-50]%	£[0-5]m
Viatris[125]	[5-10]%	£[0-5]m
Other	[0-5]%	£[0-5]m
Total	100%	£[5-10]m

Source: MIDAS IQVIA, Parties' submissions, third-party submissions.

156. This segment of the market is highly concentrated with four suppliers accounting for over 99% of total supply. Femoston accounts for almost half of the market with only one other competitor in a comparable size. The Merged Entity would be the largest supplier of oral combined continuous products with a share of [40-50]%,

[123] Parties' Response to the Issues Letter, page 36.
[124] During the issues meeting, Theramex explained that combined products may also be preferable for certain vulnerable patient groups (eg incarcerated women or women in challenging life circumstances) who might face particular challenges adhering to a regime involving multiple products.
[125] Viatris Elleste Duet to be sold by Insud.

with an increment of [<5]%. Pre-merger, Theramex is one of only two other suppliers that have a share of over 1%.

157. Since Theramex's Bijuve entered the UK market in September 2021 and was accepted onto its first formulary in January 2022, it was one of only two oral combined continuous products whose sales revenue grew. The other is Viatris' Elleste Duet Conti whose revenues grew by £[✂] from 2020 to 2023.[126] Femoston Conti's and Novo Nordisk's revenues fell over the same period, by [✂].[127]

6.3.2.1.4 Conclusion on shares

158. The shares analysis shows that market for systemic HRT is highly concentrated, with the Parties and Besins Healthcare accounting for [80-90]% of the market. The Merger involves the largest supplier of systemic HRT products in the UK and the competitor supplying the most successful oral combined continuous and sequential products. The Merger strengthens Theramex's already very substantial position in this market. The Merged Entity would be the largest or second-largest supplier in all market segments except for the progestogen-only segment. The CMA considers that the Parties' shares indicate the relative importance of the HRT products that they sell in the UK.

159. All other suppliers have smaller shares and narrower portfolios than Theramex. Apart from the Merged Entity, Besins Healthcare is the only remaining supplier of HRT with a share above 5%. No other suppliers have a share above 5% across all systemic HRT. Within particular product types, other suppliers have shares larger than 5%, but their shares are smaller than the Merged Entity's products' for all product types except one (ie Besin's Oestrogel).[128] The set of smaller suppliers include Novo Nordisk and Viatris[129] which principally supply oral combined products and several suppliers of just transdermal oestrogen-only products, such as Norgine, Novartis and Gedeon Richter.

6.3.2.2 Internal documents

160. The CMA requested a range of internal documents from the Parties to understand the competitive dynamics in HRT in the UK.

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[126] Annualised figure for 2023. Elleste Duet Conti's sales revenue [✂] before [✂] (on an annualised basis).
[127] Annualised figures for 2023.
[128] Besins Healthcare's transdermal oestrogen-only product has larger revenues than Theramex's Evorel oestrogen-only transdermal product.
[129] Viatris' Elleste product range, which represents [✂] of its revenues beyond Femoston, has been sold to Insud Pharma.

6.3.2.2.1 Theramex as a competitor

161. Internal documents (including a presentation of [✂] and a number of internal presentations between [✂]) indicated that a core parameter of competition for Theramex is to compete strongly on the promotion of [✂] products to relevant clinicians, including positioning [✂] as a [✂] alternative [✂].[130]

6.3.2.2.2 Closeness between Theramex's products and Femoston

162. The CMA considers that internal documents indicate that Theramex's products compete against Femoston in systemic HRT, and that Bijuve competes particularly closely with Femoston Conti.

163. Pre-Merger internal documents showed that Theramex viewed Femoston Sequi as a [✂] competitor to Evorel Sequi, [✂] as well as Viatris' Elleste Duet and a few smaller competitors. Theramex's pre-Merger internal documents also show that that there is a competitive interaction between Femoston Conti and Theramex's transdermal products (ie Evorel).[131]

164. Several internal documents covering Theramex's post-Merger marketing strategy indicate that Theramex intends to target its outreach in relation to Femoston Conti, Evorel and Bijuve [✂]. For example, [✂], states that a strategy has been proposed 'to [✂]' based on [✂]'.[132] An internal presentation on the Merger dated [✂] states that 'Management have developed a strategy [✂] which should also [✂]'.[133] The CMA notes that this is [✂] which sets out a strategy to address the concerns that may arise from the Merger. In a section of the document setting out [✂]. Taken in the round, the CMA considers that this document indicates that Theramex believed its products were sufficiently close to the rights that there was

[130] Theramex Internal Document Annex Q9.016 to the FMN, slides 2, 20-21 and 32;
Theramex Internal Document Annex Q10.024 to the FMN, slides 55 and 58; Theramex Internal Document Annex Q9.017 to the FMN, slides 2,7, 32-36, 50; Theramex Internal Document Annex Q10.008 to the FMN, slides 12,14, 29, 53 and 56; Theramex Internal Document Annex LL00000973, submitted to the CMA in response to s109 1, slide 23. Specifically, these documents show Theramex's intention to heavily promote Bijuve as the [✂] oral combined systemic HRT product, with the goal of [✂] Femoston Conti in particular and becoming the [✂] in the oral combined segment.
The evidence available to the CMA also suggests that Viatris also conducts active marketing [✂] (Viatris Internal Document Annex CMA_000032 in response to s109 1, page 2).
The CMA has also seen several internal documents covering Theramex's substantial promotional efforts for [✂]. These documents indicate that Theramex considers marketing and educational efforts to [✂], in addition to educational efforts for [✂], to be a central tool in increasing product sales and gaining market share from competitors across its portfolio. Theramex Internal Document Annex Q10.008 to the FMN, slide 6 and 14. Theramex Internal Document Annex LL00000973 in response to the CMA's S109 1, slides 23, 27, 30-34, 47-48 and 53; Theramex Internal Document Annex LL00012018 in response to the CMA's S109 1, slide 60. The CMA notes that this last document highlights Femoston as being a [✂].
[131] See for example Annex 10.066 to the FMN.
[132] For example, Theramex Internal Document Annex LL00017054, slide 45.
[133] Theramex Internal Document Annex LL00018222, page 3.

a risk of [✂], and had specifically considered how to address this risk in its post-Merger strategy.

165. As for the closeness between Bijuve and Femoston Conti specifically, several Theramex internal documents created around the time of Bijuve's launch show that Theramex identified Femoston Conti as a threat and outline Theramex's plan to [✂] directly from Femoston Conti by [✂] and emphasising the [✂] aspects of Bijuve.[134] Other internal documents also show that Theramex viewed Femoston Conti as the closest competitor to Bijuve.[135]

166. In addition, Theramex prepared a formulary pack to promote Bijuve and to influence [✂] to recommend that Bijuve was accepted onto [✂]. The formulary pack identified Bijuve as a [✂] rival to Femoston Conti, noting that it was the same cost but with a superior progesterone element. Theramex indicated that its strategy was to [✂] Femoston Conti.[136] While Theramex briefly mentioned a number of other combined continuous oral products in a table entitled 'Comparator costs', none of these other products were mentioned in detail.[137]

6.3.2.2.3 Discussion of other competitors' HRT products

167. The CMA has only seen only a limited number of documents that also mention or analyse other competitors or their products. [✂] were generally identified in Theramex's documents, which were either [✂] that were prepared around the time or shortly after Bijuve's launch.[138,139,140] Separate products were mentioned in one [✂] document as 'indirect competitors' to Bijuve.[141] Bijuve's formulary pack mentioned [✂] as cost comparators.[142] Femoston Conti was mentioned in all of these documents, while other competitors tend to be given less prominence (for example in the formulary pack, which listed a number of competitor products but identified and discussed Femoston Conti as direct rival to Bijuve).

6.3.2.2.4 Conclusion on internal documents

168. The CMA considers that Theramex's internal documents suggest that the Parties compete strongly against each other across product types and within the specific

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[134] Annex Q10.010 to the FMN, slide 6. Annex Q9.017 to the FMN, slide 20.
[135] See for example Annex Q10.063 to the FMN, slide 8, stating that 'Femoston Conti is the [✂] comparator to Bijuve.' and a further document states [✂]. This same internal document states that: '[✂]'.
[136]Theramex's Internal Document Annex *Bijuve Formulary Kit*, in response to s109 2, page 24., p.5, 13 and p.24.
[137] Theramex's Internal Document Annex *Bijuve Formulary Kit*, in response to s109 2, page 24.
[138] Theramex Internal Document Annex Q9_017 to the FMN, page 20.
[139] Theramex Internal Document Annex Q10.007 to the FMN.
[140] Theramex' Internal Document Annex LL00001282 in response to the CMA's s109 1, slide 8. Activelle is another name for Novo Nordisk's Kliovance.
[141] Theramex Internal Document Annex LL00013963 in response to the CMA's s109 1, slide 19.
[142] Theramex's Internal Document Annex *Bijuve Kit*, in response to the S109 2, page 24.

product type of oral combined continuous products. Theramex views Femoston Conti as a direct competitor to Bijuve and Femoston Sequi as a direct competitor to Evorel Sequi.

169. The evidence suggests that Theramex's post-Merger strategy would be to position Theramex's products and Femoston as complementary in order to avoid the risk of [✂], which suggests that the products are close substitutes. The internal documents available to the CMA also suggest that Theramex considers only [✂] and [✂] separate products as alternatives to its HRT products, although these products are given less prominence than Femoston.

6.3.2.3 Price negotiations with DHSC

170. The CMA considered evidence from Theramex's previous price negotiations with DHSC regarding Bijuve to further assess the closeness of competition between Bijuve and Femoston Conti. The CMA also considered the general context of DHSC's regulation of prices for systemic HRT products to evaluate the potential scope for the Merged Entity to increase prices post-Merger.

6.3.2.3.1 Evidence on closeness of competition from Bijuve's price negotiations

171. As set out above in paragraph 78, a branded product's initial price is set by DHSC. The product's supplier suggests a price level and a set of comparator products to compare this suggested price against. DHSC can accept, negotiate or reject the suggested price and it may also consider other comparator products.

172. As part of its strategy for aligning Bijuve with Femoston, when Theramex submitted an application to DHSC for an initial price for Bijuve, it applied for a price of £[✂] per 28 days, identical to the price of [✂].[143] Theramex suggested a set of comparator products containing a mixture of combined continuous oral and transdermal products:

(a) [✂] and three third-party combined continuous [✂] products, [✂]; and

(b) [✂] and [✂], combined continuous transdermal products owned by [✂].

173. Theramex did not include any [✂] and [✂] products in its comparator set.

174. The Parties submitted that Theramex chose [✂] as their suggested price for [✂] because it was the [✂] oral combined continuous product and not due to their clinical similarity.[144]

[143] Submission to the CMA from a third party, December 2023.
[144] Parties' Presentation in Issues Meeting, Slide 8 and Parties' Response to Issues Letter, p. 47

175. DHSC told the CMA that it had understood that Theramex considered that the products that it had included in its competitor set were relevant comparators to Bijuve.[145] DHSC accepted Theramex's suggested price for Bijuve.[146] DHSC told the CMA [✂].[147] The CMA notes that the accepted price was higher than the prices of Orion's Indivina (£6.86) and Viatris' Elleste Duet Conti (£5.67).[148]

6.3.2.3.2 Wider context of DHSC price negotiations for systemic HRT products

176. Theramex submitted that there was no scope for unilateral price increases to the NHS list price by any supplier of HRT products due to price regulation and stated that any increases must be renegotiated and approved by DHSC.[149] For these reasons, it submitted that the Merged Entity would be prevented from increasing prices post-Merger.[150]

177. However, DHSC told the CMA that it had recently approved price increase applications for systemic HRT products, including for [✂].[151]

178. Additionally, DHSC told the CMA that it assessed the availability of comparator products to assess price increase applications for products with concerns over their security of supply or discontinuation.[152] Demand for systemic HRT has grown substantially in recent years (see paragraph 152).

6.3.2.3.3 Conclusion on price negotiations with DHSC

179. The CMA considers that Theramex's choice of comparators in its initial price negotiation with DHSC reflects the group of products that it considered were viable alternatives to Bijuve. DHSC's acceptance of this comparator set reflects that it too considered them to be viable alternatives to Bijuve. Theramex's decision to price Bijuve at [✂] indicates that it considered and [✂] Bijuve to be a direct competitor of Femoston Conti.

180. While prices are regulated by DHSC, the evidence indicates that prices are not fixed, and have changed, in particular in response to supply shortages. While price increases may require negotiation with DHSC, it is not the case that there would be no scope for price increases post-Merger.

[145] Submission to the CMA from a third party, December 2023.
[146] Submission to the CMA from a third party, December 2023.
[147] Submission to the CMA from a third party, December 2023.
[148] Theramex's Internal Document Annex *Bijuve Formulary Kit*, in response to the S109 2, page 24.
[149] Parties' Response to Issues Letter, paragraph 36.
[150] Parties' Response to Issues Letter, paragraph 21(a) and page 37.
[151] Third-party submission to the CMA, December 2023, questions 2 and 3; third-party submission to the CMA, January 2024, question 6.
[152] Third-party submission to the CMA, January 2024, questions 4-6.

6.3.2.4 Analysis of Bijuve's commercial position

181. To further assess the closeness of competition between the Parties within oral combined continuous products, the CMA looked at Bijuve's current commercial position.

6.3.2.4.1 Parties' submissions

182. The Parties submitted that Bijuve was a relatively new product that had [✂] success being accepted onto formularies and had [✂] commercial success to date.[153] In particular, the Parties submitted that Bijuve had significantly [✂] Theramex's internal forecasts for its sales growth, achieving only [✂]% and [✂]% of its revenue target in [✂] and [✂] respectively.[154] Theramex submitted that it had [✂] its revenue forecasts in [✂] but Bijuve still [✂] these [✂] expectations by [✂]%.[155]

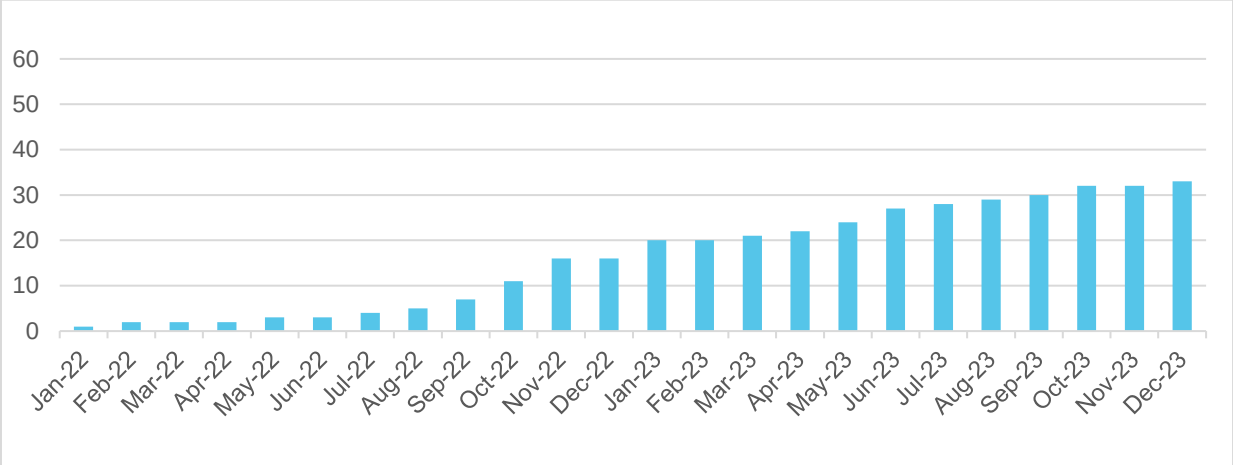
183. Theramex submitted that Bijuve was a niche product for patients with [✂] and for which Femoston Conti was not suitable.[156] The Parties submitted that the fact that Femoston Conti had not been removed from the formularies which Bijuve had been accepted onto was evidence that Bijuve was not successfully '[✂]' Femoston Conti as Bijuve's formulary pack advocated for (see paragraph 166).[157] However, the Parties also told the CMA that formularies did not usually remove systemic HRT products from their formularies as others were added.[158]

6.3.2.4.2 CMA's formulary analysis

184. To evaluate the Parties' submission that Bijuve has had [✂] commercial success generally and specifically at being accepted onto local area formularies, the CMA analysed the uptake of Bijuve at local area formularies over an 18-month period from its first acceptance in January 2022 to December 2023.

[153] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 16-19.
[154] Parties' Response to Issues Letter, paragraph 14 and Figure 1.
[155] Parties' Response to Issues Letter, paragraph 31 and Figure 2.
[156] Parties' Response to Issues Letter, paragraph 14.
[157] Parties' Response to Issues Letter, paragraph 14(c).
[158] Parties' Oral Submissions in Issues Meeting.

Figure 1: Cumulative Local Area Formulary Uptake of Bijuve, 2022-2023



Source: CMA analysis of the Parties' data.[159]

185. Figure 1 shows:

(a) Since its launch in September 2021, Bijuve has been accepted onto 36 of the 67 local area formularies in the UK, which represents c.50–55% of the relevant patient population.[160] Bijuve has been accepted onto [✂] formulary to which it has applied, except for [✂] for which its [✂].[161]

(b) Of the 31 local areas where Bijuve is not on the formulary, it is under review in [✂] areas (c. [✂]% of the relevant patient population) and Theramex plans to submit applications for Bijuve in [✂] new areas (c. [✂]% of the relevant patient population).

186. By comparison, Femoston Conti has been accepted onto [✂] local area formularies (c. [✂]% of the patient population). The Parties overlap in [✂] of the [✂] local areas where Bijuve has been accepted onto the formulary. Femoston Conti is also on the formulary in [✂] of the [✂] areas in which Theramex plans to submit an application for Bijuve and in [✂] of the [✂] areas where Bijuve's application is under review.

187. The CMA's analysis shows that Bijuve has been successful at being accepted onto formularies where it has applied to be accepted.

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[159] Parties' submission in response in response to the CMA's RFI2 Annex 0001.Q4.
[160] Certain Integrated Care Board areas contain multiple Clinical Commissioning Groups. For these areas, when a product is on the formulary of one but not all of the relevant Clinical Commissioning Groups within that area, the product is treated as being available in the Integrated Care Board area. This is only relevant for a small number of areas. The relevant patient population is identified using the proxy of females aged 45-64.
[161] The CMA understands that a product temporarily accepted onto the formulary will be available to prescribe for clinicians in that local area for a limited time period, before its application is reviewed and the product is either permanently accepted or removed from the formulary.

6.3.2.4.3 Conclusion on Bijuve's commercial position

188. The evidence indicates that Bijuve has [✂] its forecasts and has [✂] been as commercially successful as Theramex initially anticipated. The formulary analysis, however, shows that Theramex has invested in promoting Bijuve and has won acceptance onto around [✂] of the formulary local areas. Since receiving its first formulary acceptance in January 2022, Bijuve has grown its sales to £[✂] in the first nine months of 2023 and gained a share of [0-5]% in oral combined continuous segment. While the share is modest, it represents a material increment in a market that is highly concentrated and in which the Merged Entity would have the largest and fourth largest product in that market segment. The CMA also notes that Theramex is planning to gain acceptance onto more formularies, which may improve Bijuve's ability to win more sales and [✂] its commercial success.[162]

189. Therefore, the CMA considers that its analysis of Bijuve's commercial position indicates that it competes closely against other oral combined continuous products and most notably Femoston Conti.

6.3.2.5 Evidence from HRT prescribing documents guidance

6.3.2.5.1 The Parties' submissions

190. The Parties submitted that NICE, BMS and DHSC guidance documents indicated that:

(a) Bijuve's closest competitors were separate products with a micronised progesterone oral product combined with an oral oestrogen product.[163]

(b) Femoston Conti's closest competitors were other oral combined treatments with synthetic progestogens.[164]

(c) Femoston Sequi's alternatives were other oral combined treatments with synthetic progestogens or separate products.[165]

(d) Evorel Sequi's alternatives were separate transdermal oestrogen-only products combined with a progestogen.[166]

[162] The CMA received adjusted forecasts for Bijuve along with the Parties' Response to the Issues Letter but given that they were prepared after the CMA's investigation had started, the CMA could place only limited weight on them.
[163] Parties' Response to Issues Letter, paragraph 13(a).
[164] Parties' Response to Issues Letter, paragraph 13(b).
[165] Parties' Presentation at Issues Meeting, Slide 15.
[166] Parties' Presentation at Issues Meeting, Slide 15.

6.3.2.5.2 Evidence from guidance documents

191. A BMS guidance document on HRT listed suitable products for patients who should take particular types of systemic HRT. Bijuve and Femoston Conti were presented close alternatives, being identified as first and second option among oral combined continuous products.[167]

192. That same BMS guidance lists the Parties' products as the first, or first and second choice of treatment within each systemic HRT product segment apart from the progestogen-only product segment.[168] As such, the Parties' products were presented as alternatives to each other for those patients for whom multiple product types were clinically appropriate.

193. The guidance from NICE was closely aligned to the BMS guidance.[169]

6.3.2.5.3 Conclusion on evidence from guidance documents

194. The guidance documents available to the CMA indicate that HRT products within the same product type are likely to be closer alternatives to each other than products in different product types.

195. The CMA considers that clinical guidance suggests that different product types are broadly substitutable for each other and, therefore, that the Parties' products of different types are alternatives for one another. Accordingly, the evidence from clinical guidance does not support the Parties' submissions on the alternatives to Femoston Sequi and Evorel Sequi.

196. Additionally, and contrary to the Parties' submissions, the CMA considers that clinical guidance suggests that Bijuve and Femoston Conti are close alternatives to each other.

6.3.2.6 Third-party evidence (clinicians, formularies and competitors)

197. The CMA gathered evidence from clinicians, local area formularies and competitors on the demand-side substitutability of different types of systemic HRT products and the competitive strength of particular products and of different suppliers.

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[167] 15-BMS-TfC-HRT-preparations-and-equivalent-alternatives-JAN2024-B.pdf (thebms.org.uk) (last accessed 26th March 2024).
[168] Hormone replacement therapy (HRT) | Prescribing information | Menopause | CKS | NICE (last accessed 22nd March 2024).
[169] Hormone replacement therapy (HRT) | Prescribing information | Menopause | CKS | NICE (last accessed 22nd March 2024).

6.3.2.6.1 Third-party views on the strength of HRT suppliers

198. Competitors identified Theramex as a strong supplier of systemic HRT.[170] One rival said that Theramex was a strong innovator, citing the licensing of Bijuve and the commercial success of the Evorel patch over other patch products.[171] Another suggested that Theramex was successful at [✂] other products' supply shortages and that its current market position was adversely affecting others by, for example, reducing their access to clinicians to promote their products. This competitor considered the increased entry barriers from VPAG, and product launch costs reinforced Theramex's position.[172] One competitor identified Theramex as the most effective provider of education on systemic HRT, noting its investment in marketing and innovation.[173]

199. Viatris, including the Rights, was also identified by competitors as a strong supplier of HRT and received the second highest ranking.[174] Orion, Sandoz and Gedeon Richter were ranked lower than both Theramex and Viatris.[175] Competitors identified Gedeon Richter, Viatris and Orion as suppliers that were effective in providing education on systemic HRT but noted that Sandoz was a poor provider of education.[176] One supplier told the CMA that larger suppliers with broader portfolios were better positioned to promote their products and that Theramex in particular had the best access to clinicians, to the detriment of its competitors.[177]

200. Clinicians also identified Theramex as the strongest provider of education and promotion of systemic HRT alongside Viatris (including the Rights).[178] Clinicians considered Bayer, Gedeon Richter and Besins Healthcare to be weaker providers of education and promotion compared to Theramex and Viatris. One clinician suggested that suppliers with multiple systemic HRT products were better able to promote their products to clinicians and that ideally, from the supplier's perspective, all the types of systemic HRT products would be in their product portfolio.[179]

201. Based on the evidence above, competitors and clinicians consider Theramex to be a strong supplier of systemic HRT competitor. Third parties considered that its broad portfolio of HRT products conferred scale benefits for the promotion of systemic HRT products. Viatris, with the context of having the Femoston and

[170] Note of a call with a third party, December 2023, paragraph 30. Note of a call with a third party, January 2024, paragraph 44-52. Note of a call with a third party, January 2024, paragraph 18.
[171] Note of a call with a third party, December 2023, paragraphs 14 and 30.
[172] Note of a call with a third party, January 2024.
[173] Response to the CMA questionnaire from a number of third-parties, February 2024, question 14.
[174] The CMA asked competitors to list the suppliers they considered to be the main competitors for the supply of systemic HRT and to list the suppliers that were most effective in providing education on systemic HRT.
[175] Response to the CMA questionnaire from a number of third-parties, February 2024, question 5.
[176] Response to the CMA questionnaire from a number of third-parties, February 2024, question 14.
[177] Note of a call with a third party, January 2024, paragraphs 29 and 51.
[178] Response to the CMA questionnaire from a number of third-parties, February 2024, question 7.
[179] Note of a call with a third party, November 2023, paragraph 32.

Femoston Conti within its portfolio, was also seen as a strong competitor. Other competitors, including Besins Healthcare, were viewed as less strong suppliers of systemic HRT and providers of education/promotion than Theramex.

6.3.2.6.2 Third-party ranking of individual products

202. The CMA asked clinicians to rank the HRT products that they considered most suitable to prescribe for postmenopausal patients who have not had a hysterectomy and could take oral products. The clinicians who responded identified 11 products in total, of which the Merged Entity would supply four.[180] In terms of ranking:

(a) Half of the clinicians identified Femoston Conti as their preferred treatment option (ie first). One of these clinicians also ranked Bijuve joint first with Femoston Conti, while another ranked Bijuve second.

(b) Kliovance (from Novo Nordisk) was the only other combined continuous oral product identified by a clinician, and it was ranked third behind Femoston Conti and Bijuve.[181]

(c) Theramex's Evorel Conti was the only combined continuous transdermal product identified. It was identified by one clinician who ranked it second behind Femoston Conti and Bijuve.

(d) Half of the clinicians identified only separate oestrogen-only and progestogen-only products as suitable treatment options with the combination of Besins Healthcare's Utrogestan and a transdermal oestrogen-only element as their first choice. One identified the combination of Utrogestan with one of Oestrogel, Lenzetto or Evorel as first choice, with Provera and the Mirena IUS as alternatives to Utrogestan. Another identified the combination of Utrogestan and just Evorel, with Estradot as a back-up to Evorel.

203. In their qualitative assessments of the respective products, clinicians noted that Bijuve and Femoston Conti were the closest alternative for patients who required 1mg of oestrogen, as Bijuve is only available with a 1mg dosage.[182] Clinicians also indicated that body-identical hormones were clinically superior, owing to their reduced risk of harmful side-effects such as higher risk of blood clots or strokes than compared to synthetic hormones (body-identical hormones include

[180] Response to the CMA questionnaire from a number of third-parties, February 2024, question 5.
[181] In response to a separate question on products which are viable alternatives to oral and transdermal HRT, one clinician noted that for the small proportion of patients for whom their ranked products (which included Femoston Conti, Bijuve, Evorel Conti) were ineffective, Kliovance, Kliofem and Elleste Duet were alternatives (Response to the CMA questionnaire from a number of third-parties, February 2024, question 6).
[182] Note of a call with a third party, November 2023, paragraph 20; Note of a call with a third party, November 2023, paragraph 23.

micronised progestogen, which is used in Bijuve).[183] Another clinician said that dydrogesterone (which is used in Femoston) carried lower risk factors similar to body-identical progesterone, and that synthetic progestogens other than dydrogesterone should not be used unless there were supply shortages in body-identical progesterone and dydrogesterone products.[184]

204. The CMA asked the clinicians to rank the HRT products that they considered most suitable to prescribe for perimenopausal patients who have not had a hysterectomy and could take oral products. A number of clinicians responded and they identified seven products in total, of which the Merged Entity would supply three.[185] In terms of ranking:

(a) Around half of the clinicians identified Femoston Sequi as their preferred treatment option (ie first).

(b) Viatris' Elleste Duet was the only other combined sequential oral product identified by one clinician, and it was ranked second behind Femoston Sequi.

(c) Theramex's Evorel Sequi was identified by around half of clinicians. It was ranked second behind Femoston Sequi once and once fourth behind Femoston Sequi, Elleste Duet and a combination of a transdermal oral product with micronised progesterone (ie Utrogestan).

(d) The combination of Utrogestan with a transdermal oestrogen-only element was identified by a majority clinicians as suitable, with two ranking it as their first choice.[186]

205. The evidence received from formularies was broadly consistent with the evidence from clinicians. In particular, Femoston Conti and Bijuve were identified as a strong option for oral products for postmenopausal patients, alongside Novo Nordisk's Kliovance/Kliofem and Viatris' Elleste Duet Conti.[187]

206. Evidence from clinicians and formularies on the clinical applicability of individual products matched their views on the overall substitutability of different product types, ie that different product types were broadly substitutable. When identifying suitable products, they often identified a mix of oral and transdermal products and of separate and combined products, with their preferences varying across each product type. Some clinicians had stronger preferences for particular product types

[183] Note of a call with a third party, November 2023, paragraph 8-10. Note of a call with a third party, November 2023 paragraphs 11 and 17; Note of a call with a third party, November 2023, paragraph 6.
[184] Note of a call with a third party, November 2023, paragraph 36.
[185] Response to the CMA questionnaire from a number of third-parties, February 2024, question 5.
[186] One identified the combination of Utrogestan with one of Oestrogel, Lenzetto and Evorel as first choice, with Provera and the Mirena IUS as alternatives to Utrogestan. The other identified the combination of Utrogestan and just Evorel, with Estradot as a back-up to Evorel. Another clinician who identified the combination of Utrogestan (or Mirena) with Oestrogel or Evorel ranked it third behind Femoston Sequi and Elleste Duet.
[187] Response to the CMA questionnaire from a number of third-parties, February 2024, question 8.

than others, for example only listing separate treatments with transdermal oestrogen or just oral combined products. The CMA notes that one formulary, which sought to guide clinicians' prescribing choices, had a clear preference for combined products, consistently ranking them over separate products.

207. In line with their views on the broad substitutability of different product types, the CMA considers that the evidence from clinicians and formularies suggests that the Parties' oral and transdermal products compete against each other. Specifically, Theramex's Evorel Conti and Evorel products compete against Femoston Conti, and Theramex's Evorel Sequi and Evorel products compete against Femoston Sequi. Evorel was seen as one of the two strongest oestrogen-only products.

208. The evidence from clinicians and formularies suggests that Bijuve and Femoston Conti compete particularly closely against each other within the oral combined continuous product type segment. Despite Bijuve's [✂] it was identified by a number of clinicians and formularies as being a strong, if not the strongest, product.

209. Separate products were also identified by clinicians and formularies as alternatives to the Merged Entity's combined products. Clinicians and formularies identified separate products with a similar frequency to combined products, with some ranking them as more suitable than combined products and others as less suitable. Separate products' rankings suggest that separate and combined products are considered substitutes to each other, but not as close substitutes as within product type segments.

210. With respect to separate products, Besins Healthcare's Oestrogel was the main oestrogen-only product identified, followed by Theramex's Evorel, with Gedeon Richter's Lenzetto product also identified but to a lesser extent than Oestrogel and Evorel. Other oestrogen-only products which have UK MA were either not identified or identified as a weaker alternative. Besins Healthcare's Utrogestan was the principal progestogen-only product identified, alongside others including the Mirena IUS.

211. Novo Nordisk's Kliovance/Kliofem and Viatris' Elleste Duet Conti were the only other combined continuous oral products identified as alternatives to Bijuve and Femoston Conti. They were identified fewer times, although one formulary ranked Kliovance/Kliofem as superior to Femoston Conti and Bijuve. Elleste Duet was identified as the main combined sequential alternative to Femoston Sequi and Evorel Sequi, although it was only ranked as superior to Femoston Sequi by one formulary.

6.3.2.6.3 Third party views on the Merger

212. Clinicians and competitors raised concerns to the CMA about security of supply and that it might be profitable for the Merged Entity to withdraw products from its portfolio, for example withdrawing its less profitable products to increase demand for its more profitable products.[188] Formularies also raised concerns about security of supply.[189] However, one clinician told the CMA that Theramex has a good reputation for ensuring stability of supply.[190]

213. Competitors' views on the Merger were mixed. One suggested that it would have no impact on them.[191] Another stated that the Merger would increase Theramex's dominant market position, particularly with respect to product promotion. This competitor indicated concerns around security of supply and about the potential withdrawal of products.[192] Another competitor said that the Merger between its two strongest competitors would reduce competition.[193]

6.3.2.6.4 Conclusion on third-party evidence

214. The CMA considers that evidence from competitors and clinicians indicates that Theramex is considered to be a strong competitor, especially on product promotion. Third parties commented on the strength of Viatris as a supplier of HRT, with the context that it would compete on the basis of its current HRT portfolio. Other HRT suppliers were considered to be less strong competitors.

215. Theramex's products were identified by clinicians and formularies as competing against Femoston. Theramex's Evorel Sequi and Evorel were identified as strong alternatives to Femoston Sequi. Theramex's Evorel Conti, Evorel and Bijuve products were identified as strong alternatives to Femoston Conti. In particular, Bijuve was frequently identified as being a close alternative to Femoston Conti, with clinicians noting the similarity of their progestogen elements.

216. Some separate products and some combined oral products were identified as alternatives to the Merged Entity's products. Besins Healthcare's Oestrogel was the main oestrogen-only product identified as an alternative, alongside Lenzetto. Novo Nordisk's Kliofem/Kliovance and Viatris' Elleste Duet Conti were the main alternative combined continuous products identified.

217. Overall, the evidence from clinicians, formularies and competitors suggests that Theramex is a very strong competitor, and that its products compete closely with Femoston. The Merged Entity would face a limited number of competitive

[188] Response to the CMA questionnaire from third parties, February 2024, question 8.
[189] Response to the CMA questionnaire from a third party, February 2024, question 11.
[190] Response to the CMA questionnaire from a third party, February 2024, question 8.
[191] Response to the CMA questionnaire from a third party, February 2024, question 8.
[192] Response to the CMA questionnaire from a third party, February 2024, question 8.
[193] Response to the CMA questionnaire from a third party, February 2024, question 8.

constraints from separate products, principally Besins Healthcare's, and oral combined products supplied by Viatris (now Insud Pharma) and Novo Nordisk.

6.3.2.7 The CMA's assessment on the impact of the Merger on the supply of systemic HRT in the UK

218. In order to assess whether the removal of the constraint that the Parties place on each other as a result of the Merger would lead to an SLC in the supply of systemic HRT in the UK, the CMA assessed the evidence set out above on how closely the Parties compete with each other and on the extent of the competitive constraints placed on the Parties by other HRT suppliers. The evidence indicates the competition for the supply of systemic HRT takes place across several parameters, including product promotion, product range development, price and security of supply.

219. While the CMA identified a market for all systemic HRT products, the evidence set out above indicates that products of the same type are most substitutable for each other, and competition is at its most intense between products of the same type.

220. The market for systemic HRT is highly concentrated with the Parties and Besins Healthcare accounting for over 80% of revenue. The Merged Entity would have a very significant share of supply of systemic HRT at [4-50]%, with an increment of [5-10%] in an already concentrated market.

221. Theramex is the largest supplier of systemic HRT in aggregate. It is the only supplier of combined sequential and combined continuous transdermal products and the second largest supplier of oestrogen-only transdermal products. The Merger would add the most successful oral combined continuous product, Femoston Conti, and the most successful oral combined sequential product, Femoston Sequi, to Theramex's already extensive portfolio. As such, the Merged Entity would have the first or second most commercially successful product in five of the six main product type segments (ie apart from progestogen-only products).

222. The evidence indicates that the Parties compete closely with each other on the key parameters of competition in the supply of branded systemic HRT products. Third parties told the CMA that Theramex competes effectively on product promotion and was identified by competitors as being an innovative supplier relative to its rivals, with a considerable promotion presence. Third parties also identified Viatris – with the Femoston products in its portfolio – as a strong competitor and effective on product promotion. The evidence indicates that the Parties, along with other HRT suppliers, have been able to negotiate price increases with the DHSC, in response to supply shortages. The Parties have also introduced developments and innovations to their product range.

223. The Parties compete particularly closely through their oral combined continuous products, Femoston Conti and Bijuve. Theramex promoted Bijuve as a close alternative to Femoston Conti, including by [✂] its price to Femoston Conti's. Bijuve was identified by clinicians, formularies and in the clinical prescribing guidance as a close alternative to Femoston Conti. Theramex's internal documents show that it had a strategy for Bijuve to [✂] Femoston Conti and, post-Merger, Theramex would seek to promote the products as targeted at [✂] to avoid [✂]. While Bijuve has performed [✂] than anticipated by Theramex, its relatively modest share to date should be considered in the context where the Merged Entity would have a [40-50]% share in a highly concentrated segment. Further, Theramex has had some success in expanding the presence of Bijuve, with the product being accepted in around half of the local area formularies, and Theramex is planning to gain acceptance in more local areas. This would likely improve Bijuve's ability to [✂] and compete more strongly in future.

224. In addition, the CMA does not accept the Parties' claims that the oral combined product type segments are insignificant overall. Their revenues have fallen in absolute terms and relative to other product types due to current patient preferences for transdermal and for separate products. However, based on the evidence gathered by the CMA, including the Parties' other statements,[194] the CMA understand that as the market grows and more awareness is raised among clinicians and patients, there is some growth potential for the oral combined continuous segment. In any event, the CMA considers this segment to be very important on the basis that it may be preferable for certain group of patients, potentially including vulnerable patients, to rely on a combined pill.

225. Theramex and Femoston compete against each other across product type segments. Specifically for the Parties' products, the evidence directly indicates that Femoston Conti competes against Theramex's other HRT products, principally Evorel Conti which is its transdermal combined continuous product, and Evorel, its transdermal oestrogen-only product. While there are differences between oral and transdermal products for certain patients, clinicians consistently listed Evorel Conti and Evorel alongside Femoston Conti in their rankings of suitable products for postmenopausal patients. Theramex's internal documents suggest that there would be a risk of [✂] of sales between Femoston Conti and Evorel, which it would need to proactively mitigate post-Merger.

226. Within sequential treatments, the evidence from clinicians, formularies, guidance documents and Theramex's internal documents suggests that Femoston Sequi competes against Evorel and Evorel Sequi. Clinicians consistently listed Evorel and/or Evorel Sequi alongside Femoston Sequi in their rankings of suitable

[194] Parties' Oral Submissions in Issues Meeting.

products for perimenopausal patients. Theramex's internal documents suggest that it considers its combined transdermal products compete against oral products such as Femoston Sequi. Accordingly, the CMA considers that Theramex's transdermal sequential products compete closely with Femoston Sequi.

227. Overall, taking all of the evidence in the round, the CMA considers that the Parties are close competitors for the supply of systemic HRT in the UK. Currently, Femoston is an alternative to Theramex for patients and clinicians choosing between oral combined continuous products and for those choosing between product types. Post-Merger this constraint would be lost. The Merged Entity would supply the first- or second-most successful product in five of the main six product segments. Patients and clinicians would have fewer suppliers to choose between when selecting between product types. Given how highly concentrated the supply of systemic HRT is, the loss of competition is significant.

228. The CMA considered whether the remaining competitive constraints on the Merged Entity might offset the loss of constraint between the Parties as a result of the Merger. Across all systemic HRT, the only other supplier with a substantial share is Besins Healthcare, with a [30-40]% share. It does not offer any combined products, but it is the largest supplier of oestrogen-only transdermal products and progestogen-only products. As such, it would likely exert a competitive constraint on the Merged Entity. No other supplier has a share of more than 5% and all other suppliers' shares, with the exception of Gedeon Richter, have fallen since 2020. Third parties told the CMA that these suppliers were weaker competitors on product promotion than the Parties. The CMA considers that the constraint from these other smaller HRT suppliers is likely to be weaker than the Parties have on each other.

229. Based on its assessment, the CMA considers that the Merger removes a significant constraint between the Parties across the overall HRT systemic market and within the individual product segments, and that the remaining constraints from Besins Healthcare and the tail of smaller HRT suppliers mentioned above are unlikely to be sufficient to offset the loss of constraint brought about by the Merger.

230. The loss of competition resulting from the Merger is likely to lead to worse outcomes in the supply of systemic HRT, and in particular suppliers' product promotion and product range development. While prices are regulated, the reduction of alternatives available to DHSC in a market that is already highly concentrated reduces choice and gives rise to concerns about the security of supply and potential price increases at times of stock shortages.

6.3.3 Conclusion on horizontal unilateral effects in the supply of systemic HRT products in the UK

231. For the reasons set out above, the CMA considers that the loss of competition between the Parties would not be sufficiently offset by the remaining competitive constraints it would face. Accordingly, the CMA considers that the Merger gives rise to a realistic prospect of an SLC as a result of horizontal unilateral effects in the supply of systemic HRT in the UK.

6.4 Loss of future competition in the supply of dydrogesterone

232. Horizontal unilateral effects may arise from the elimination of future competition where, absent the merger, entry or expansion may have resulted in new or increased competition.[195] When considering whether a merger involving a potential entrant leads to a loss of future competition between the merging parties, the CMA will consider evidence on:[196]

(a) whether either party would have entered or expanded absent the merger; and

(b) whether the loss of future competition brought about the merger would give rise to an SLC, taking into account other constraints and potential entrants.

6.4.1 Market definition

233. Market definition involves identifying the most significant competitive alternatives available to customers of the merger parties and includes the sources of competition to the merger parties that are the immediate determinants of the effects of the merger.[197]

6.4.1.1 Product market

234. Viatris owns the rights to market and sell Duphaston in the UK, which is an off-patent synthetic progestogen-only product based on the dydrogesterone molecule. Duphaston has not been sold in the UK since 2008 when the previous product owner withdrew the MA in the UK.[198] As explained above, Duphaston was withdrawn from the market at a time when there were concerns about the safety of HRT. Clinical assessments of the safety of HRT have since been revised and there is now significant and growing demand for HRT. No dydrogesterone-only products are currently being sold in the UK. As discussed in the Counterfactual section, absent the Merger, the CMA considers that Duphaston would have been

[195] CMA129, paragraph 5.1–5.4.
[196] CMA129, paragraph 5.7.
[197] CMA129, paragraph 9.1.
[198] FMN, paragraph 229 and footnote 106.

relaunched and Theramex would have introduced a generic dydrogesterone product into the UK. Within this context, the narrowest overlap would have been the supply of dydrogesterone in the UK.

235. The CMA considered whether the relevant product market should be limited to the dydrogesterone molecule or whether it should be broadened to include other progestogens, or other systemic HRT products, having particular regard to the nature of competition being changed by the first generic entry of dydrogesterone, as explained below.

6.4.1.2 Parties' submissions

236. The Parties submitted that defining the product market as the supply of dydrogesterone was too narrow. The Parties submitted that dydrogesterone products would still compete in varying degrees with other synthetic progestogens. Further, the Parties submitted that patients could switch from one progestogen to another where there was a change in medical circumstance.[199] The Parties also submitted that where a dydrogesterone product had been prescribed, and there were generic versions of such products available, prescriptions would specify the molecule and that would reflect the choice of which molecule was most appropriate at that point (see paragraph 82 on the prescription process).[200]

237. The Parties further submitted that the market should also include other progestogen-only products and estradiol-dydrogesterone molecule combinations that would compete with a dydrogesterone product. The Parties told the CMA that there were several progestogen-only products that were already offered in the UK, and a number of estradiol-dydrogesterone molecule combinations (where dydrogesterone is taken as the progestogen element of combined HRT) being developed.[201]

238. The Parties submitted that there was not any unmet demand for dydrogesterone in the UK, as Besin's Utrogestan, a micronised progesterone, was the only major player in the progestogen-only segment although alternative progestogen-only products were available, such as Gepretix (a generic micronised progesterone) and Mirena Coil.[202]

6.4.1.3 Third-party views

239. A third party told the CMA that there were only two oral bioidentical progesterone-only HRT products available in the UK: Besins Healthcare's Utrogestan which is

[199] Parties' response to Issues Letter, page 93.
[200] Parties' response to Issues Letter, page 93.
[201] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraphs 50-52.
[202] Parties' response to Issues Letter, 7 March 2024, page 93.

based on micronised progesterone and a generic version of the same product, Insud Pharma's Gepretix (which launched in the UK in 2023).[203]

240. Another third party submitted that, whilst micronised progesterone products (which are bioidentical progesterone products) were similar to dydrogesterone in terms of biochemical structure, dydrogesterone was considered to be better tolerated than synthetic progestogen. One clinician stated that dydrogesterone carried fewer side effects than other synthetic progestogens.[204] Accordingly, offering both micronised progesterone and dydrogesterone would widen the range of alternatives available to patients.[205] Clinicians also told the CMA that having more progestogen options would be beneficial as patients could respond differently to dydrogesterone and micronised progesterone.[206] In particular, they submitted that there was an unmet clinical need in the UK for dydrogesterone specifically.

241. DHSC said that if bioequivalent products were prescribed generically (no branded product is specified) the pharmacist had a choice of which product to dispense. DHSC stated that the NHS reimbursement level was the same for all generics, regardless of the drug chosen. DHSC told the CMA that prescribing by molecule was common even in cases where only one product was available, although DHSC was not aware of practices in HRT specifically.[207]

6.4.1.4 CMA assessment

242. Dydrogesterone products are synthetic progestogens and would offer clinicians a further alternative to the body-identical micronised progesterone products available. The third-party evidence set out above also indicates that there is likely to be unmet demand for dydrogesterone products in the UK. The CMA considers that this view is consistent with Theramex's launch plans for a dydrogesterone product in the UK which are further set out below.

243. At a broad level, and when physicians are selecting which products to prescribe, dydrogesterone products would be included in the systemic HRT market discussed in theory of harm 1. Within that market, standalone dydrogesterone products may compete particularly closely with alternative progestogen-only products, in particular micronised progesterone.

244. With respect to dydrogesterone in particular however, competitive dynamics would be expected also to reflect the introduction of one or more generic products into the market. As explained above, when a generic version of a medicine is available, prescribers will typically issue open prescriptions specifying the molecule rather

[203] Note of a call with a third party, January 2024, paragraph 24. Note of a call with a third party, January 2024.
[204] Note of call with a third party, November 2023, paragraph 39.
[205] Submission to the CMA from a third party, January 2024, question 1(b).
[206] Note of a call with a third party, November 2023, paragraph 21. Note of call with a third party, January 2024, paragraph 39.
[207] Note of call with a third party, January 2024, paragraph 22.

than an individual named product. At that point, pharmacists are free to dispense either the branded or the generic version of that molecule (and dispensing decisions will typically be made on the basis of price, as explained in more detail above). This also means that, once a prescription is written, products that are not bioequivalent, such as micronised progesterone, are not generally substitutable for the prescribed molecule. On this basis, the CMA considers that when products have been genericised, there is a specific product market for the molecule. This approach is consistent with the CMA's decisional practice and an approach that has been accepted by the Competition Appeal Tribunal.[208]

245. As regards combined products containing both oestrogen and dydrogesterone (of which the only current examples are Femoston Sequi and Femoston Conti, which are both part of the Rights), the CMA considers that these products cannot be substituted at the point of dispensing, given they contain another hormone, oestrogen, and can only be prescribed in fixed doses as opposed to individual component products. On this basis, the CMA does not consider these are close substitutes to dydrogesterone-only products.

6.4.1.5 Conclusion on product market

246. Based on the evidence above, the CMA has concluded that the relevant product market is the supply of dydrogesterone (both originator and generic). The CMA will take into account the competitive constraint of other progestogen-only products in its competitive assessment where appropriate.

247. The CMA notes that its approach to identifying the relevant market for dydrogesterone once it is 'genericised' differs from its approach when assessing horizontal unilateral effects in the supply of systemic HRT. The difference in the CMA's approach reflects the substantially different competitive processes between medicines in the absence of generic entry and after generic entry as set out above in section 6.1.1.1 .

6.4.1.6 Geographic market

248. The Parties stated that the relevant geographic market was the UK. This was on the basis that both the European Commission and CMA had previously defined geographic markets for pharmaceutical products as national in scope, due to the fact that regulatory and reimbursement systems operate at national level.

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[208] *Generics (UK) Limited and others v CMA* [2018] CAT 4, paragraph 402; *Anticipated acquisition by Actavis UK Limited of Auden Mckenzie Holdings Ltd* 2015 [ME/6513/15] (**Actavis/Auden**), paragraphs 43 and 49. In Actavis/Auden, the CMA recognised that generic pharmaceuticals normally represent the closest substitute to originator products and that there is generally limited demand-side substitutability between generic pharmaceuticals of different molecules. The CMA therefore assessed the merger by reference to the originator and generic pharmaceuticals of the same molecule.

249. As set out at paragraph 137 above, the CMA received no evidence to suggest that significant differences exist across the UK nations.

6.4.1.7 Conclusion on geographic market

250. The CMA has concluded that the relevant geographic market for the supply of dydrogesterone is the UK.

6.4.1.8 Conclusion on market definition

251. The CMA has concluded that the relevant product market is the supply of dydrogesterone (both originator and generic) in the UK.

6.4.2 Competition assessment

252. The CMA assessed whether it is or may be the case that the Merger has resulted, or may be expected to result, in an SLC arising from the loss of future competition in dydrogesterone, in particular owing to the loss of generic entry.

253. As set out in the Counterfactual section above, the CMA considers that there is evidence that absent the Merger, Theramex would have launched a generic dydrogesterone in the UK in partnership with [✂] (see section 5) and that an alternative purchaser, eg [✂], would have relaunched Duphaston in the UK (see section 4.1.2.1).

254. As also explained above, shortly before the Merger was agreed, Theramex terminated the [✂] Agreement, so Theramex is no longer expected to introduce a generic dydrogesterone product into the UK. Even if the [✂] Agreement had not been terminated, the Merger would have resulted in the Duphaston rights and the [✂] Agreement being held by the same entity rather than by competitors.

255. The CMA has considered what alternative constraints will remain in the market for dydrogesterone following the Merger.

6.4.2.1 Likelihood of [✂] entering the market for dydrogesterone products in the UK with a different partner

256. The CMA has considered the likelihood of [✂] entering the market for dydrogesterone products in the UK with a different partner.

6.4.2.1.1 Parties' submissions

257. The Parties told the CMA that there were no obstacles to [✂] finding an alternative partner to commercialise the generic dydrogesterone that it was developing. Theramex did not consider that it offered [✂] any unique capabilities.[209]

258. The Parties submitted that there are multiple suitable third parties who could partner with [✂], and identified potential credible buyers active in UK's women's health, including Gedeon Richter, Besins Healthcare, Bayer and Novartis.[210] The Parties also suggested that [✂] bidder for the Rights (which included Duphaston) must be likely to be interested in partnering with [✂] to launch the [✂] product if it had been interested in acquiring and relaunching Duphaston.[211]

259. Further, the Parties submitted that [✂] had stated that it would not stand in the way of the termination of the [✂] Agreement and that this behaviour suggested that [✂] believed that it could find a new partner.[212]

260. The Parties submitted that experience from generic markets more generally suggests that initial generic entry typically prompts further attempts to follow. The Parties therefore suggested that entry by another generic third party dydrogesterone would increase the likelihood of the [✂] product being launched.[213]

6.4.2.1.2 Internal documents

261. Theramex's internal documents suggested that Theramex believed that the [✂] of the originator Duphaston was [✂] than that of a generic dydrogesterone. Theramex identified that Duphaston had a [✂], while a generic dydrogesterone [✂].[214]

6.4.2.1.3 Third-party evidence

262. Third party evidence indicated that [✂] does not have the capabilities to commercialise its generic dydrogesterone product without the aid of a commercialisation partner.[215]

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[209] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraphs 47-48.
[210] Parties' response to Issues Letter, paragraph 146.
[211] Parties' response to Issues Letter, paragraph 22(c).
[212] Parties' response to Issues Letter, paragraph 42
[213] Parties' response to Issues Letter, paragraphs 24-26.
[214] LL00016727, slide 19.
[215] Note of a call with a third party, January 2024.

263. The CMA therefore gathered evidence from relevant third parties to understand the likelihood and timing of [✂]'s entry with a partner other than Theramex.[216]

264. The evidence received by the CMA from a number of sources indicated that it is uncertain whether [✂] will secure a partner to market its generic version of dydrogesterone in the UK.

6.4.2.1.4 CMA assessment

265. If [✂] obtains an MA in the EU, this may increase the attractiveness of a partnership with [✂] to third parties. However, the evidence above indicates that there is currently uncertainty as to whether [✂] will secure a commercialisation partner to market its generic dydrogesterone product in the UK. Even if [✂] were to secure a new partner, to replace the constraint previously provided by Theramex in the UK market, it would be necessary that the new commercialisation partner had the ability and incentive to launch a generic product in the UK.

266. The CMA does not consider that, as suggested by the Parties, a third party's interest in acquiring Duphaston must indicate that it would also be interested in partnering with [✂]. This is supported by Theramex's internal documents that suggest Duphaston had [✂] as the branded originator product, and Theramex's decision to terminate its partnership with [✂] in favour of acquiring the Duphaston rights. As a result, it is not clear that a potential purchaser of the Duphaston rights can be assumed also to be interested in entering into a partnership with [✂].

267. The CMA has not found sufficient evidence to conclude that the [✂] generic product is likely to be introduced into the UK through a partnership with a third party. On that basis, the CMA considers that the loss of Theramex as a commercialisation partner will impair the entry of [✂]'s generic dydrogesterone product in the UK relative to the counterfactual.

6.4.2.2 Likelihood that the impairment of [✂]'s generic entry would give rise to an SLC

6.4.2.2.1 Parties' submissions

268. The Parties submitted that any dydrogesterone product would compete with several progestogen-only products already offered in the UK, including micronised progesterone (such as Besins Healthcare's Utrogestan) and other synthetic progestogens.[217] The Parties, however, also submitted that molecular composition

[216] Note of a call with a third party, January 2024; third party response to RFI, January 2024; third party response to section 109 notice, February 2024; third party response to section 109 notice, February 2024
[217] Parties' response to Issues Letter, page 92.

was the most important factor in determining closeness of competition and there were significant differences between micronised progesterone and dydrogesterone.[218]

269. The Parties also submitted that dydrogesterone would compete against a number of estradiol-dydrogesterone molecule combinations (where dydrogesterone is taken as the progestogen element of combined HRT).[219] Femoston is the only estradiol-dydrogesterone available in the UK.[220] However, the Parties submitted that [✂].[221]

6.4.2.2.2 Third-party evidence

270. Clinicians told the CMA that body-identical progesterone products (ie micronised progesterone) and dydrogesterone were clinically superior to synthetic progestogens. The NICE guidance identified that patients have different tolerances to different progestogens with dydrogesterone being less androgenic than some synthetic progestogens and more similar to micronised progesterone. Another third party told the CMA that dydrogesterone was very similar in biochemical structure to micronised progesterone, and it was considered better tolerated than other synthetic progestogens. Some clinicians indicated that dydrogesterone can have benefits over micronised progesterone, at least for certain patients.[222]

271. A number of clinicians told the CMA that having more progestogen options would be beneficial as patients may respond differently to dydrogesterone and micronised progesterone. Some clinicians submitted that there was an unmet clinical need in the UK for dydrogesterone specifically (see paragraph 240).

272. The CMA has seen evidence that one third party is independently developing a generic dydrogesterone product that would be bioequivalent to Duphaston, the originator product. Based on the available evidence, the CMA considers that it is likely that this product will be launched in the UK.

6.4.2.2.3 CMA assessment

273. For the reasons set out above, the CMA is assessing the Merger against a counterfactual in which a generic dydrogesterone would have been launched by Theramex in partnership with [✂], and Duphaston would have been relaunched by an alternative purchaser. The CMA has also found that there is one third party that may enter the UK with a generic dydrogesterone product. As a result of the

[218] Parties' response to Issues Letter, page 45.
[219] Stragen's Zalkya, Bayer's Primolut and Pfizer's Depo Provera were listed by the Parties as examples of progestogen-only products. Parties' submission on the CMA's emerging thinking, 15 February 2024, footnote 20.
[220] FMN, paragraph 173.
[221] Parties' submission on the CMA's emerging thinking, 15 February 2024, paragraph 51.
[222] Note of a call with a third party, November 2023, paragraph 39. Note of a call with a third party, November 2023, paragraph 19.

Merger, the entry of [✂]'s generic dydrogesterone into the UK would be impaired. There would therefore only be two dydrogesterone-only products likely to be made available to clinicians in the UK, ie Duphaston and a third-party entrant.

274. Duphaston and generic dydrogesterone-only products will be bioequivalent and near perfect substitutes at the point of prescription, and as such the CMA would expect there to be price competition between Duphaston and any generic dydrogesterone-only products. The loss of the [✂] generic is expected to materially weaken the intensity of competition. The CMA found in past cases that the intensity of competition, particularly on price, reflects the number of generic products in the market (see paragraph 96). The CMA therefore considers that the reduction in the number of potential competitors from three to two would have a significant impact on the intensity of competition that would have taken place absent the Merger which may result in higher prices for UK patients.

275. The CMA notes that, while – based on the available evidence – it considered it likely that a third-party generic would launch irrespective of the Merger, its entry remains uncertain at this point. If the third-party entry does not ultimately take place, post-Merger, there would be no dydrogesterone constraint on Duphaston. In any case, as indicated above, the CMA does not consider that one third-party entry would be sufficient to offset the loss of the [✂] generic, given that there would be only two competing products on this market.

276. With respect to the constraints from other progestogen-only products, as explained in the assessment of market definition (see section 6.4.1), the CMA considers that dydrogesterone, once genericised, is likely to compete most closely against other dydrogesterone products (both originator and generic). As explained in the market definition section, based on the available evidence, the CMA does not consider that other synthetic progestogens are likely to be viable alternatives at the point of dispensing and therefore to constrain dydrogesterone.

6.4.3 Conclusion

277. For the reasons set out above, the CMA considers that the Merger gives rise to a realistic prospect of an SLC as a result of the loss of future competition in the supply of dydrogesterone in the UK.

7. ENTRY AND EXPANSION

278. Entry, or expansion of existing firms, can mitigate the initial effect of a merger on competition, and in some cases may mean that there is no SLC. The CMA will consider entry and/or expansion plans of rivals who do so in direct response to the merger as a countervailing measure that could prevent an SLC. In assessing

whether entry or expansion might prevent an SLC, the CMA considers whether such entry or expansion would be timely, likely and sufficient.[223]

279. The Parties submitted that there are minimal barriers to entry and expansion for current competitors and new entrants, noting that the Rights are off-patent, and submitting that there is significant development of generic products against off-patent systemic HRT products generally.[224]

280. The evidence available to the CMA suggested that there are significant barriers to entry and expansion for the supply of new systemic HRT (including generics).[225] For example, the development of an entirely new product is expensive and complicated, and it may take years, with a significant risk of failure along the process: a third party described the process as 'hugely complex' and liable to cost in the region of £2 billion from beginning to end.[226] Developing a generic drug is less complex but the costs and risks are still substantial: a third party told the CMA that developing a generic may involve multiple attempts, with each failure costing in the region of $500,000.[227] In addition, as explained above, a new generic product must obtain marketing authorisation in the UK. Therefore, in assessing the impact of potential entry, the CMA has taken into account the progress of each product (or lack thereof) in obtaining an MA from the MHRA.

281. The CMA has not seen evidence of entry that is likely to take place in response to the Merger. In its competitive assessment above, the CMA considered any potential entry that may occur irrespective of whether the Merger proceeds. With the exception of the generic progestogen products that the CMA considered in its assessment of the counterfactual and its competitive assessment (see paragraph 272 above), the evidence available to the CMA indicates that no timely, likely or sufficient entry of products which would compete closely against the Merged Entity is expected.

282. Accordingly, the CMA has not found evidence of entry that would be timely, likely or sufficient to prevent a realistic prospect of an SLC as a result of the Merger.

8. CONCLUSION ON SUBSTANTIAL LESSENING OF COMPETITION

283. Based on the evidence set out above, the CMA believes that it is or may be the case that the Merger may be expected to result in an SLC as a result of horizontal

[223] CMA129, paragraph 8.31.
[224] FMN, paragraph 10(iv).
[225] Note of a call with a third-party, January 2024, paragraphs 18 and 19-23.
[226] Response to the CMA questionnaire from a competitor, February 2024.
[227] Note of a call with a third party, January 2024.

unilateral effects in relation to the supply of HRT in the UK and as a result of a loss of future competition in relation to the supply of dydrogesterone in the UK.

9. EXCEPTIONS TO THE DUTY TO REFER

284. Where the CMA's duty to refer is engaged, the CMA may, pursuant to section 33(2)(a) of the Act, decide not to refer the merger under investigation for a phase 2 investigation on the basis that the market(s) concerned is/are not of sufficient importance to justify the making of a reference (the de minimis exception). The CMA considered whether it is appropriate to apply the de minimis exception to the present case.

285. The Parties submitted that a number of segments and increments are de minimis and the theory of harm in relation to dydrogesterone relates to a market without turnover. Therefore, the Parties submitted that the CMA should consider whether the duty to refer applies.[228]

286. The CMA notes that the market concerned in relation to the supply of systemic HRT exceeds £100 million in the UK and is growing, which is well above the £15m threshold set out in the Mergers: Exceptions to the duty to refer guidance (the **De Minimis Guidance**).[229] In any event, as set out in the De Minimis Guidance, when considering the magnitude of competition lost by a merger, the CMA will have regard to whether a substantial proportion of the likely detriment would be suffered by vulnerable customers. The CMA notes that the competitive detriment would be suffered by patients seeking medical treatment, and that if loss of competition resulting from the Merger led to higher prices, these would likely be borne by the NHS. The CMA considers that given these markets relate to an important set of medical treatments that a large number of patients rely on in the UK, even if the market size did fall below the de minimis threshold, it is unlikely that the CMA would conclude that these were markets of "insufficient importance", and that an exception to the duty to refer would apply in this case.

10. CONCLUSION ON THE APPLICATION OF THE DE MINIMIS EXCEPTION

287. Taking all the above factors into consideration, the CMA believes that the market(s) concerned in this case are of sufficient importance to justify the making of a reference. As such, the CMA believes that it is not appropriate for it to exercise its discretion to apply the de minimis exception.

[228] Written response to the Issues Letter, page 108.
[229] Mergers: Exceptions to the duty to refer (**CMA64**), 13 December 2018, paragraph 20.

DECISION

Consequently, the CMA believes that it is or may be the case that (i) arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation; and (ii) the creation of that situation may be expected to result in an SLC within a market or markets in the United Kingdom.

The CMA therefore believes that it is under a duty to refer under section 33(1) of the Act. However, the duty to refer is not exercised whilst the CMA is considering whether to accept undertakings under section 73 of the Act instead of making such a reference.[230] The Parties have until 11 April 2024[231] to offer an undertaking to the CMA.[232] The CMA will refer the Merger for a phase 2 investigation[233] if the Parties do not offer an undertaking by this date; if the Parties indicate before this date that they do not wish to offer an undertaking; or if the CMA decides[234] by 18 April 2024 that there are no reasonable grounds for believing that it might accept the undertaking offered by the Parties, or a modified version of it.

Sorcha O'Carroll
Senior Director, Mergers
Competition and Markets Authority
4 April 2024

[230] Section 33(3)(b) of the Act.
[231] Section 73A(1) of the Act.
[232] Section 73(2) of the Act.
[233] Sections 33(1) and 34ZA(2) of the Act.
[234] Section 73A(2) of the Act.